

**FULL COMMITTEE HEARING ON  
LEGISLATION TO IMPROVE THE  
REGULATORY FLEXIBILITY ACT**

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**COMMITTEE ON SMALL BUSINESS  
UNITED STATES HOUSE OF  
REPRESENTATIVES**

**ONE HUNDRED TENTH CONGRESS**

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## **FULL COMMITTEE HEARING ON LEGISLATION TO IMPROVE THE REGULATORY FLEXIBILITY ACT**

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**Thursday, December 6, 2007**

**U.S. HOUSE OF REPRESENTATIVES,  
COMMITTEE ON SMALL BUSINESS,  
Washington, DC.**

The Committee met, pursuant to call, at 10:06 a.m., in Room 2360, Rayburn House Office Building, Hon. Nydia M. Velázquez [chair of the Committee] Presiding.

Present: Representatives Velázquez, González, Cuellar, Altmire, Clarke, Ellsworth, Chabot, and Akin.

### **OPENING STATEMENT OF CHAIRWOMAN VELÁZQUEZ**

Chairwoman VELÁZQUEZ. I call this hearing to order to address legislation to improve the Regulatory Flexibility Act. Today the committee is reviewing legislation to strengthen the Regulatory Flexibility Act, or Reg Flex. Passed into law in 1980, Reg Flex has played a critical role in ensuring that American small businesses are not overly burdened by Federal regulations. While the act has improved this process in many ways, small firms are still more affected by regulations than are their larger counterparts. The reality is that more must be done to address this problem that can hurt our overall economy.

Last month, this committee took the first step in identifying ways to improve Reg Flex. We heard from small businesses representing a diverse group of industries on ways to craft legislation to strengthen the act. There was one clear thing present in the testimony. Agencies are not doing enough to consider the impacts of the rules and regulations of small businesses. And more effective statute can help reduce unnecessarily burdensome regulations.

Working with the minority, the small business community and with input from the SBA Office of Advocacy, the committee has drafted legislation which addresses a number of the deficiencies of Reg Flex. One of the goals of the legislation is to address the problem of outdated regulations. The committee print will clarify when agencies need to review specific rules. It also gives small businesses a greater voice in the process and enhances transparency, helping to eliminate unnecessary burdens. The committee also wants to ensure that agencies are not ignoring the underlying requirements of Reg Flex. The act was never intended to completely eliminate or slow down regulations, but for agencies to consider if there are more effective alternatives to meet policy goals. Too often

agencies avoid fully analyzing the impact of the rules on small businesses by certifying that a rule will have no significant consequences. This bill will strengthen the analysis requirements by compelling agencies to consider reasonably foreseeable, indirect economic impacts on small businesses when writing rules.

One key recommendation from the Office of Advocacy was to codify Executive Order 13272, which is included in the legislation. This chain puts in the statute that there must be greater coordination between agencies and the SBA's Office of Advocacy, ensuring that regulators fully consider the economic impacts on small firms. Earlier notification will provide Advocacy with a greater opportunity to assist agencies in Reg Flex compliance.

This print we are reviewing today is by no means a final version. Today's panelists will discuss how this language can help small businesses and identify ways it can be improved. I would like to thank all the witnesses today for coming to the committee and sharing their views. I look forward to continuing our work with Ranking Member Chabot to pass meaningful reform to the Regulatory Flexibility Act which will lessen burdens on small businesses and allow our Nation's entrepreneurs to continue to move our economy forward.

I would now like to yield to Ranking Member Chabot for his opening statement.

#### **OPENING STATEMENT OF MR. CHABOT**

Mr. CHABOT. Thank you, Madam Chairwoman, for holding this hearing on legislation to strengthen the Regulatory Flexibility Act. New small businesses open every year. Buffeted by a variety of economic and financial hardships, these businesses struggle mightily to achieve a profitable bottom line. Small businesses are particularly affected by unnecessary and burdensome regulations that require more money as a percentage of the money that the small businesses have to work with and time than their larger competitors to adequately comply.

Small businesses, according to a study by the Office of Advocacy of the United States Small Business Administration, paid \$2,000 more per employee per year than large businesses to comply with the tornado of Federal regulation. In some sectors, such as manufacturing, the per employee cost is even higher than that average. The unfortunate but unexpected result is hundreds of thousands of small business are forced to shut their doors.

More than 25 years ago Congress recognized there was a regulatory storm brewing and smartly reacted with legislation to force Federal regulators to examine the impact that their rules will have on small businesses before inadvertently putting them out of business. Congress' answer to the regulatory problem was called the Regulatory Flexibility Act, or RFA. Enactment of the RFA forced a small but perceptible shift in the tact of Federal regulation. While some agencies were prompted to refocus their thinking and develop less burdensome regulation, many others treated the RFA as merely suggestion and were undeterred on their course for more and more burdensome and overlapping regulation.

Congress attempted to strengthen the RFA in 1996 by enacting the Small Business Regulatory Enforcement Fairness Act. The act

made agency compliance with the procedural requirements of the RFA judiciously reviewable, independent of any challenge to the underlying agency rule. With the threat of litigation hanging over them, Federal agencies began paying more attention to the RFA, but the added attention did little to increase cooperation for many agencies.

The valiant efforts of Dr. John Graham and Mr. Tom Sullivan, one of our witnesses today, attempted to tame the tidal wave of Federal bureaucracy. And while they admirably eliminated many problems in the system, we have not seen the dramatic change small businesses require, as evidenced by many small firm owners that have come before this committee requesting help and by the many businesses forced to shut down each year.

The efforts of Chief Counsel Sullivan have been hampered by the inadequacy of the RFA. Plagued by undefined terms and vague parameters, the RFA is far from an ideal statute. Existing loopholes permit agencies to circumvent the rules with negligible penalties.

Last year I cosponsored H.R. 682, a bill designed to significantly strengthen the RFA so that agencies, as President Bush stated, quote, will care that the law is on the books, unquote. The bill under consideration today adopts some of the changes that were in H.R. 682 by requiring agencies to consider indirect effects, to provide a more detailed assessment of the impacts and to make the periodic review of rules more transparent. These changes will help to ensure that small businesses need only endure necessary regulations and that agencies will not be able to create new ones to harm or destroy these businesses.

Whenever Congress considers altering the RFA, opponents argue that changes would destroy the regulatory process or overwhelm Federal courthouses. Examination of the Federal Register and courthouses show they remain strong, despite the supposed strength of the RFA hurricane. Ultimately, what is at stake is the ability of small businesses to stay in business based not on the whims and dictates of Federal bureaucrats but on their capacities in the marketplace.

Better, sounder rules will be beneficial to the regulatory objectives of the agencies through increased compliance and lower costs to small businesses. No good reason exists to oppose the goals and objectives of this bill other than the fear of the unknown. I stand ready to work with the Chairwoman to see that we get a much stronger version of the RFA. I thank her for holding this hearing, and I will yield back the balance of my time.

Chairwoman VELÁZQUEZ. Thank you. Are there any other members who seek recognition for the purpose of making an opening statement? Mr. Ellsworth.

#### **OPENING STATEMENT OF MR. ELLSWORTH**

Mr. ELLSWORTH. Thank you, Madam Chair. I would like to take a moment to thank you for holding this important hearing. Ranking Member Chabot, thank you for your work on this also and then your statement that you just gave. I think this is a very important issue for this committee to undertake, and I look forward to what the member, Mr. Sullivan, what you have to say and the members who come in the next panel.

A few weeks ago we had our first hearing on the Regulatory Flexibility Act. It became clear to me that the problems are serious the way the Federal Government is treating small businesses and that is—I have said this about every meeting I have spoke at. That is why I asked to join this committee, to make things easier for small businesses.

We also heard from the operator of a small trucking firm who was here and I asked him what kind of impact the Uniform Federal Regulations had on his business. He told me it hurt his business and others like him. It was clear that big corporate trucking firms and their teams of lawyers and compliance officers had a leg up on the small business. I am all for big trucking companies, but we also have to look after the small trucking companies. As we all know, the small companies in our districts are facing the same burden. The Federal Government has ignored effects of our regulations on small businesses and refused to adjust to the needs of the vital employers. This is not a small business problem, and it is not a small problem at all. 1,250,000 workers are employed by small business in my home State of Indiana and they deserve to have their voices heard. To the bureaucrats in Washington, sometimes this doesn't seem like a small problem. We lose sight of that. But to Hoosier small businesses it is.

That is why I am glad we are addressing this issue, the draft of the bill before us today, and I look forward to hearing from today's witnesses and working with everyone in the future to solve this problem. Thank you. With that, I yield back.

Chairwoman VELÁZQUEZ. Any other member who seeks recognition? Ms. Clarke.

#### **OPENING STATEMENT OF MS. CLARKE**

Ms. CLARKE. Thank you very much, Madam Chair and to Ranking Member Chabot, for holding this hear today to review legislation to improve the Regulatory Flexibility Act. There is no question that Reg Flex needs to be strengthened. Agency compliance with many parts of the act is of great concern to me and must be addressed immediately since most agencies currently view compliance as voluntary. I believe that we will develop solid provisions that will consider the indirect impact of regulations when calculating the impact of regulations on small businesses.

I look forward to hearing from the Honorable Sullivan today so that we can work together for a solution that will enable our small businesses to prosper and not be inundated and snuffed out by undue harm that this act was put in place to prevent.

Thank you very much, Madam Chair.

Chairwoman VELÁZQUEZ. Any other members? If not, now we will proceed with our first panel. And I want to welcome Mr. Thomas Sullivan, the Chief Counsel for the Office of Advocacy of the U.S. Small Business Administration. Prior to joining the SBA, he worked as the Executive Director of the National Federation of Independent Businesses Legal Foundation. Mr. Sullivan and the Office of Advocacy is charged with independently advancing the views, concerns and interests of small businesses before Congress, the White House, Federal regulatory bodies and State policy-makers. Welcome, Mr. Sullivan.

**STATEMENT OF THE HON. THOMAS M. SULLIVAN, CHIEF  
COUNSEL, OFFICE OF ADVOCACY, U.S. SMALL BUSINESS AD-  
MINISTRATION**

Mr. SULLIVAN. Thank you, Chairwoman Velázquez, Ranking Member Chabot, and members of the committee. Thank you for allowing me the opportunity to appear this morning to address legislative improvements to the Regulatory Flexibility Act. With the chairwoman's permission, I would like to briefly summarize my statement but ask that the entire statement be entered into the record.

Chairwoman VELÁZQUEZ. Without objection.

Mr. SULLIVAN. Thank you. As the chairwoman said, in my position I am charged with monitoring Federal agencies' compliance with the Regulatory Flexibility Act. And because my office is an independent one within SBA, the views that I express here this morning don't necessarily reflect the views of the administration or of SBA. My statement was not circulated to the Office of Management and Budget for comment.

Although the Reg Flex Act is doing a fairly good job, and I do want to emphasize the fact that the Reg Flex act is working pretty well, but despite it doing a fairly good job and achieving cost savings for small entities, more does need to be done to protect small entities from excessive regulatory burden.

Two years ago, my office commissioned a study that was prepared by Mark Crain entitled the impact of regulatory costs on small firms. This is the third iteration of such a study and it determined that the overall cost of Federal regulation now totals \$1.1 trillion. I will say that again. \$1.1 trillion with a T, a trillion dollars. The cost per employee for firms with fewer than 20 employees is \$7,640 per employee per year. That is 45 percent higher than their larger counterparts with 500 or more employees.

After 11 years of working with SBREFA, eight congressional hearings on the Regulatory Flexibility Act, my office has conferred this past year on the Regulatory Flexibility Act, and several GAO reports and testimonies, now is a good opportunity to consider legislative improvements to the Regulatory Flexibility Act.

At your hearing several weeks ago, many of the witnesses testified that the largest loophole is the Reg Flex Act failure to include the requirement that agencies consider indirect impacts. We agree with those witnesses before the committee and we do believe it is the biggest loophole. Agencies now are required to consider the direct economic impact, but that analysis may deprive policymakers here in Washington, D.C. Of the full understanding of the rule's likely impact on small entities.

In addition, many times, especially with environmental regulation, the duty of regulating is passed on to the States and it is passed on without any corresponding analysis or requirements for States to consider less burdensome alternatives for small business. Legislation being considered by this committee would cure that defect.

Section 610 of the Regulatory Flexibility Act requires agencies to periodically review rules that are on the books. Small businesses often complain about the difficulties in dealing with layers of regulations that agencies issue over time. Although there are legal ave-

nues that can be pursued to have burdensome rules reviewed, legal recourse is costly and time consuming. The automatic review of rules afforded through section 610 can save small entities and Federal agencies the hassle of having to resort to the legal system to obtain relief. However, as is currently written, this review is limited to only those rules that an agency deems to have a significant economic impact at the time the rule is finalized. Since new rules are promulgated every year, the cumulative impact of rules on small entities can be staggering, even if individually the rules may not have a significant economic impact.

My office and other witnesses before this committee have recommended that the Reg Flex Act be amended so that look back provision, section 610, will require agencies to review all rules periodically. This change would encourage agencies to revise their rules to ensure that regulations currently reflect current conditions and needs.

Lastly and most importantly, the codification of an Executive order that was signed in this administration. My office believes that the Executive order has increased agency knowledge of and compliance with the Regulatory Flexibility Act. Annual reports that are published by my office and presented to this committee, to the White House and others in Congress document that this Executive order is working. Small entities would benefit from an amendment to the RFA that would codify the requirements of that Executive order ensuring that independent agencies are subject to the Reg Flex Act and, since it is just an Executive order, codification would create long-term certainty for small entities.

My office has reviewed the committee print distributed last week, and the bill entitled the Small Business Regulatory Improvement Act of 2008 addresses the issues outlined in my testimony. I commend this committee for examining these issues, and I believe your legislation will go far to improve the RFA and, most importantly, help small entities.

Thank you for allowing me to present these views, and I would be happy to answer any questions.

[The prepared statement of Mr. Sullivan may be found in the Appendix on page 35.]

Chairwoman VELÁZQUEZ. Thank you, Mr. Sullivan. You discussed section 610 of Reg Flex that requires agencies to periodically review existing rules. We all know that is not working. It has been reported that this is because the law gives agencies a large amount of discretion to decide which rules are covered by the review requirement.

How should Reg Flex be amended to ensure agencies do a better job of periodically reviewing existing rules?

Mr. SULLIVAN. Madam Chairwoman, I believe that the committee print addresses this perfectly, and what the committee print does is simply instruct agencies that they must look at a broader swath of rules, not just a narrow swath of those that at the time of promulgation were deemed significant.

Chairwoman VELÁZQUEZ. Mr. Sullivan, although on this committee we hear much about the burden Federal regulations impose on small businesses, it is important to keep in mind the Federal regulations also confer enormous benefits to our society. Clean air

and water and safe working conditions are all examples of this. Opponents of Reg Flex have contended that it frustrates the rule-making process. How many rules, Mr. Sullivan, have actually been halted by the courts because of Reg Flex?

Mr. SULLIVAN. I believe that less than six rules have been struck down by agencies since 1996 in the courts and, if the Chairwoman would allow me, I would like to address this myth about the Reg Flex being a barrier to valuable regulatory protections. If you look at the number of rules that were promulgated by the Environmental Protection Agency before the Small Business Reg Enforcement Fairness Act and after, remember, SBREFA conferred a number of obligations upon EPA and this committee was faced with folks saying that this is terrible, this will stop EPA from promulgating valuable environmental protections. The average number of rules issued by EPA was 412 per year before SBREFA. The average number of EPA rules after SBREFA were 449. The average number of rules that would impact small businesses before SBREFA was 125 per year; after SBREFA, 181 rules per year that would impact small business. So the data does not support that myth that law, the Reg Flex Act, SBREFA, is a barrier to valuable protections, environmental, workplace safety and otherwise.

Chairwoman VELÁZQUEZ. Even if a rulemaking is adjudged to have violated Reg Flex, courts will permit the regulatory process to go forward if it is in the public interest. So can you discuss this and whether or not it creates substantial delays or obstacles to rulemaking?

Mr. SULLIVAN. The chairwoman again brings up somewhat of a myth in that the Reg Flex Act stops valuable rules, and I think it is valuable for the committee and others to know that the Reg Flex Act foresaw this argument and wrote directly in that the alternatives that must be considered, and I quote, must be consistent with the stated objectives of the applicable statutes. So built into the Reg Flex Act, there is the requirement that any considerations of being sensitive to the unique needs of small entities not compromise the underlying statute. And it is because of that language that the chairwoman is correct, courts have not been activists in striking down rules. And, in fact, the majority of times, when the Reg Flex Act is brought into a court and the small entities prevail upon the court to mandate that an agency do a better job, many times the rule continues to be in effect but the agency then must go back and in public and in a transparent manner document the impact on small entities so that policymakers have a better understanding of the rule's impact.

Chairwoman VELÁZQUEZ. Mr. Sullivan, some of the proponents of Reg Flex reform have called for legislation to direct the Chief Counsel for Advocacy to promulgate regulations governing agency compliance with Reg Flex. They state that currently the courts grant little or no difference to the Chief Counsel's interpretation of Reg Flex and because of this Federal agencies do not defer to Advocacy's view either.

So let me ask you, what are the benefits and drawbacks to legislation that directs Advocacy to promulgate regulations governing agency compliance with Reg Flex?

Mr. SULLIVAN. The benefits, as the chairwoman notes, in her question is that the courts are more likely to give the Office of Advocacy deference. The negative part of that is that it is a resource drain on our office that I am not sure we are prepared to meet. But if asked by the committee, I am supportive of regulatory authority, but there is a question mark on whether or not the resources of my office could support that type of effort.

Chairwoman VELÁZQUEZ. Mr. Sullivan, I am aware of concerns that requiring agencies to consider indirect economic impacts in rulemaking will bog down the regulatory process. Similar concerns were expressed during the consideration of SBREFA as the act provided for judicial review of agencies' compliance with Reg Flex. However, these fears were not born out as courts have applied a reasonableness test to agency action. The legislation we are reviewing today requires only reasonably foreseeable indirect impacts to be considered. Is "reasonable foreseeable" the proper standard to ensure the regulatory process does not grind to a halt?

Mr. SULLIVAN. In my opinion, Chairwoman, the term "reasonably foreseeable" does hit upon the appropriate standard to drive an analysis of indirect impact. I caution the committee of being more prescriptive because this is really a case of you have got to call them when you see them. There are rules that are so obviously deficient and indirect impacts.

I think one of the most obvious is if the Federal Aviation Administration issues a rule that prohibits airplanes from landing at a specific airport. I think it is reasonably foreseeable that a number of small businesses operating at this airport would be impacted. And there are many other rules that meet that reasonably foreseeable standard.

So I commend the committee for using that term and I think it is the appropriate standard.

Chairwoman VELÁZQUEZ. I have other questions, but at this point I will recognize the ranking member.

Mr. CHABOT. Thank you, Madam Chair. Thank you for being here, Mr. Sullivan. My first question is if agencies are able to assess the indirect socioeconomic effects of their major rules and environmental impact statements, how hard would it be for those agencies to prepare an initial or final regulatory flexibility analysis for indirect effects?

Mr. SULLIVAN. Well, Congressman Chabot, I cannot speak on behalf of the agencies. One, because I am not in their seat promulgating rules, but two, because of my office's independence. We don't exchange drafts of testimony prior to hearings like this. What I can inform the committee, though, is several years ago when the then called Immigration and Naturalization Service issued rules that would prohibit foreign visitors from extending their stays here in the United States and this committee, to its credit, brought in Commissioner Ziegler and myself and put him to task, to say, you know, this is so obvious that even though you are regulating travelers that you are going to impact the tourist community that is virtually all small businesses. How can you not have that type of transparent analysis? And I was sitting in the same place that I am today and to my right was the Commissioner and in front of

the Commissioner was a piece of paper with every documentation of data of indirect impacts on specific parts of the tourist industry.

So the reason I raise that is because to the agency's credit, they are doing the indirect impact and I believe that the public and the stakeholders on these rules deserve to see it. It is a matter of transparency and I do believe much of that analysis is being done, but I can't speak on behalf of the agencies on how much additional work it would be to bring transparency to the data and analysis that exists on indirect impact.

Mr. CHABOT. My next question is if the Executive order is codified, how would the Chief Counsel get proposed or final rules from independent agencies such as the Federal Communications Commission, for example.

Mr. SULLIVAN. There is really no guarantee once a law is on the books that it works. And so I believe as the committee does that codifying the Executive order would go far in helping guarantee that we get rules in a timely manner prior to promulgation. But if it doesn't work I can assure the committee I will come up and testify and work with you from an oversight capacity to make sure that it does work and that the FCC abides by its obligations under the law.

Mr. CHABOT. Thank you. Are there other agencies that you might recommend be included in the panel process in addition to the two agencies already included, the EPA and OSHA?

Mr. SULLIVAN. Congressman Chabot, this has come up before. Specifically Chairwoman Velázquez had asked shouldn't all agencies do panels. I should say in my initial first years I responded in saying that yes and we can handle the workload. The chairwoman was very patient with me at the time and asked me again a few years later could my office handle that type of workload and, with a few years more under my belt in the job I answered no, we could not. We average, I think, there are hundred—averages between 1 and 400 hours per panel. And so for the sense of resource constraints, I can't recommend that any other agencies be brought under the panel process. I would, though, make sure the committee understands that the same benefits that are derived from the panels at EPA and OSHA can be derived from compliance with the Regulatory Flexibility Act, and I would posit that when you amend the Reg Flex Act the way you are proposing to, you get the benefits of the panel process, the guaranteed small business involvement without the resources of the panels. So you are actually achieving the benefits of the panels without necessarily the resource constraints that I now know are part and parcel of the panel process.

Mr. CHABOT. My final question is, even if the Chief Counsel never filed an amicus brief, how would the so-called Chevron deference help the Office of Advocacy in their disputes with other Federal agencies?

Mr. SULLIVAN. Right now, every lawsuit that includes a valid Regulatory Flexibility Act claim does serve as a wake up call to Federal agencies to awaken them to their responsibilities under the Regulatory Flexibility Act. And in the next panel specifically, you have Marc Freedman, who was part of the effort to file a lawsuit challenging a recent Homeland Security immigration enforcement bill. So I think he may be able to give an even greater firsthand

account of how including a Reg Flex Act claim brings an agency's attention to their responsibilities under the Reg Flex Act.

In response to your question about Chevron deference, yes, I think agencies would certainly take their obligations more seriously if the Office of Advocacy or when the Office of Advocacy is afforded that type of deference by the courts.

Mr. CHABOT. Thank you. I would yield back, Madam Chair.

Chairwoman VELÁZQUEZ. Ms. Clarke?

Ms. CLARKE. Thank you, Madam Chair. And good morning to you, Honorable Tom Sullivan. On November 30th, the Food and Drug Administration issued a final rule for over-the-counter antitussive drug products. The FDA determined the final rule will not have a significant economic impact on a substantial number of entities and certify without any further analysis under Reg Flex. Do you believe that agencies can and/or are abusing Reg Flex when it comes to compliance requirements for issuing a final rule?

Mr. SULLIVAN. I don't think all agencies have it exactly right, Congresswoman.

Ms. CLARKE. Very good answer.

Mr. SULLIVAN. Thank you.

Ms. CLARKE. What would you say is the solution under what we are trying to achieve here?

Mr. SULLIVAN. I think there are a number of avenues to try to get to the solution, none of which are a silver bullet. The first part of the solution is certainly keeping my office to task in its oversight responsibilities to the Reg Flex Act. We try our best, we try to keep our ears to the rail to make sure we are attentive to small entities concerns. But we benefit from being informed of where our resources should be spent and where our priorities should be.

So I think the first part of the solution is keeping my office on task. The second part of the solution is taking steps like this to amend the Reg Flex Act now that we have a greater long-term working knowledge of it to hopefully bring more agencies into the fold in getting their analysis correctly.

The third is oversight. And I cannot overstate the importance of this committee's role in the effectiveness of the Regulatory Flexibility Act. This isn't just me. This is me and my four predecessors as the Chief Counsel of Advocacy and a number of predecessors of all of yours regardless of the party in charge who have sat on the Small Business Committee. It is through your oversight that has driven much of the success of the Regulatory Flexibility Act. So to the extent that there are flaws in an agency's analysis, part of reaching a solution is bringing them before this committee and it is part of my job also to appear before this committee to perhaps instruct agencies on how they could do a better analysis when it comes to considering their burden on small entities.

Ms. CLARKE. And when an agency certifies that a rule does not have a significant impact on a substantial number of small firms, they only provide the simplest reason for certification. Do you believe that parties are adversely aggrieved by this current process.

Mr. SULLIVAN. I don't like saying that going to court is a solution for many things when it comes to small business. In my previous job I headed a legal foundation that in fact did go to court. The cost of a district court challenge can be half a million dollars. You go

up to the appellate, the appellate level is 1-1/2 million dollars. I have not encountered any small businesses in my tenure as Chief Counsel that have 1-1/2 million dollars in reserve to challenge an agency action. So I have got to downplay the courts as being the solution. However, from a certification process, the courts have been very clear that have said the requirement that a factual basis underlie the certification is something that the courts take very seriously and the agencies should take very seriously, and I think that precedent has helped drive agencies to better comply with how they document their certification. It must—according to the courts, it must be accompanied by a factual basis.

Ms. CLARKE. I yield back. Thank you very much, Madam Chair.  
Chairwoman VELÁZQUEZ. Mr. Ellsworth.

Mr. ELLSWORTH. Thank you, Madam Chair. Mr. Sullivan, could you tell me in my allotted time about the R-3 program, how it works, who participates, how you forward that information on to the agencies, how you reach your findings in that program?

Mr. SULLIVAN. Congressman, thank you for asking about the R-3 program. R-3 stands for Regulatory, Review and Reform, and the initiative which calls for nominations for—by small entity groups to nominate rules that they believe should be reviewed to be updated, streamlined or removed. The birth of this program recently is mostly because of what we are talking about today, and that is the failure of part of the Regulatory Flexibility Act to really have agencies do a spring cleaning.

So with that type of gap, I want to both work with this committee to fix that gap legislatively, but I also want to work through an initiative to make sure that we can do everything we can even without additional legislation to bring agencies into compliance with section 610 of the Regulatory Flexibility Act.

So the R-3 initiative calls for nominations for rules that can be reviewed and reformed. We are picking the top 10 nominations for reform and we will forward those to the agencies for action in early spring in conjunction with our annual report to Congress on implementation of the Regulatory Flexibility Act. This initiative has been underway for about 2 months. We have received over 30 nominations for reform. We have narrowed that down and are very close to having a top 10. And I want to make sure that the committee knows and other stakeholders know that even though some ideas for our office's involvement in rules may not fit neatly into a top 10 list, that doesn't mean that they go into the trash can or the shredder. We will continue to work on the issues that are important.

Health care, taxes are the two issues important to small businesses. We will continue working on those, but we have heard from small businesses that we should prioritize a spring cleaning by Federal agencies to look at rules that can be updated or streamlined. The classic case on this is in the 1990s a small business owner, Bill Farren, out in Arkansas owned a number of gas stations, and he had to fill out a form that told his local fire chief that he had gas on the premise. Well, Mr. Farren thought this was absurd and he contacted Members of Congress. He contacted this committee. He contacted my predecessor and collectively you all contacted Administrator Carol Browner and she agreed with Mr.

Farren. And because of his initiative, you removed that requirement, you removed that paperwork. There have got to be other Bill Farrens out there and that is why we are undergoing this R-3 program.

So I am very optimistic of its success and I ask the committee to keep my office on task for its successful implementation and that when we do issue our top 10 rules in need of review and reform, I welcome the opportunity to come to this committee with the agencies who we identify to work together so that we can ease the burden on small business.

Mr. ELLSWORTH. How do you come up with the top 10—if the 11th one was pretty good, would you then put that in next year's or how do you discern the 10 from No. 11?

Mr. SULLIVAN. Well, Congressman, I am hoping that we have to discern 10 from the top 18. And, yes, those next 8 will go right into the next year's batch.

Mr. ELLSWORTH. Thank you very much. And I yield back.

Chairwoman VELÁZQUEZ. Thank you. Mr. González.

Mr. GONZÁLEZ. Thank you very much, Madam Chair. And welcome, Mr. Sullivan. And for everyone's edification, we met yesterday and had a very good discussion regarding what you are doing in being proactive and making sure that you gather the information that may address the shortcomings that an agency or department may have regarding identifying those regulations, rules or anything else that need some updating or actually just do away with them totally. This is two areas. If you really think in terms of an agency or department prior to the promulgation and adoption of a rule you would think that, yes, they have an obligation to go out there and see what the consequences might be. I don't think they do. I don't think that really happens. You have comment periods, but how many people really comment unless you are part of an association or organization. And the other, of course, is the periodic review, as you have already said, to go through there and do away with that which is no longer applicable or serves its purpose or you could actually improve on it. I don't think that goes on either. I don't think there is the real incentive, and that is what we are trying to develop here.

Statutorily how do we create a greater degree of accountability and the incentive? I would like to think first as you take away the excuses to the departments and the agencies that they are not aware of the impact of their regulatory scheme. Now, I also believe that this usually happens after the adoption, not prior to or during the discussion or comment period and only when we have those consequences that negatively impact small businesses. My point is what you are doing now with your own effort, I would like to see on a grander scale and charging somehow the individual agencies and departments of also being proactive on their own. You are an advocate for small business. I understand that. But for you to actually be going out to a huge universe and try to gather that information which I think you need to be doing, I just would just like to see that being replicated at every department and agency level and—whether that is possible or not.

The last hearing we had and the meeting we had yesterday was the result of course of my suggestion of having Nydia's hotline or

her Web site. I don't think she volunteered to do that. But I am really quite serious. I want the small businessman and woman in America to somehow know there is a way to plug into some sort of a system where they are able to lodge their complaint, that how it is impacting them.

And I always use the simple experiences that I have had with constituents about why does the form have to be 12 pages when you can reduce this thing to 2 pages. But try to find someone that will listen to you and even a Member of Congress doesn't get really listened to by the bureaucracy. They will wait us out and they will wear us out, and it is Senator Nelson from Nebraska said when you are talking to these guys they will say we were before you and we will be here after you. I really think that is the attitude out there.

The question is accountability. Is there something we can do first of all to assist you in your effort in the program that Congressman Ellsworth was discussing with you, and beyond that is there something that this committee can do to spread that responsibility to the individual agencies and departments?

Mr. SULLIVAN. Congressman González, thank you for your question. Thank you for meeting with me yesterday to talk about many of these things. I think first of all there is an acknowledgement that agencies are doing hundreds of reviews of their rules. So it would be untruthful for me to say that they are not doing anything. They are. I think the question is, from my perspective, do they need especially in prioritizing what they are looking at to see that they can focus specifically on those measures that would help small business, and that is really what R-3 is about. I pledge to you that I will work with you and this committee to take whatever types of steps we can not only to make R-3 an initiative but I like your suggestion of seeing if there are ways to broaden that, and I think that will become clear after our first year of running with this R-3 to see how it works.

But I do agree with you, the accountability is a huge issue. And in small businesses not feeling lost in the bureaucracy is a big issue that we—that it is good that we are trying to take on.

Chairwoman VELÁZQUEZ. Will the gentleman yield?

Mr. GONZÁLEZ. Yeah, as a matter of fact, I yield back. Thank you, ma'am.

Chairwoman VELÁZQUEZ. Mr. Sullivan, when he asked you how can we assist you and your office, I think codifying section 3 of Executive Order 13272 would allow for you to come to the rulemaking process at an early stage and I believe that will be a tool important to your office.

Mr. SULLIVAN. I agree with the chairwoman. The codification of 13272 would not only help us get small businesses' views into the process earlier, it would also empower this committee because it then becomes law not exclusively the purview of the executive branch. So I agree with the chairwoman.

Chairwoman VELÁZQUEZ. Mr. Chabot? With that we end this panel. But, Mr. Sullivan, I have all the questions that I will be submitting to you in writing for the record.

Mr. SULLIVAN. Thank you. It will be a pleasure to respond. Thank you.

Chairwoman VELÁZQUEZ. And the committee is in recess until we complete votes on the floor.

[Recess.]

Chairwoman VELÁZQUEZ. The committee is called to order and we are going to proceed with our second panel. We have Mr. Marc Freedman. He is the Director of Labor Law Policy of the U.S. Chamber of Commerce. Prior to joining the U.S. Chamber of Commerce, he was the Regulatory Counsel for the Senate Small Business Committee. At the U.S. Chamber of Commerce, Mr. Freedman is responsible for developing and advocating the Chamber's response to a variety of labor and workplace issues. The U.S. Chamber of Commerce represents over 3 million businesses.

Welcome, sir.

**STATEMENT OF MR. MARC FREEDMAN, DIRECTOR OF LABOR LAW POLICY, U.S. CHAMBER OF COMMERCE**

Mr. FREEDMAN. Thank you, Madam Chairwoman. Now that you have read my introduction, let me just point out that during my time at the Senate Small Business Committee, my role was to oversee agency compliance with the Regulatory Flexibility Act and make suggestions about ways that it could be improved. So I have been around this discussion for quite some years.

The Chamber unequivocally supports improvements of Regulatory Flexibility Act to expose loopholes and clarify various terms that have led to agencies avoiding the requirements of the act. We therefore are pleased to support your bill, the Small Business Regulatory Improvement Act of 2008, and I commend you for pursuing this issue and holding this hearing today.

If we needed a reminder—and let me just start off. The DHS "no match" reg has already been mentioned, and I would like to cite to it for a moment to give the committee an example of the length to which agencies will go to avoid the Reg Flex compliance. In that reg, as you may remember, the DHS did not address any of the complications and subtleties of trying to determine whether their regulation would have a significant economic impact on a substantial number of small entities. They basically blew right through that and went right to a legal conclusion that it did not disturb the underlying obligation of an employer to determine the work authorization of the employees and therefore there was no new burden.

As you have heard, the Chamber intervened in a case brought by an array of unions specifically to raise the Reg Flex issue. Unfortunately, the U.S. District in the Northern District of California saw through DHS's neglect of its rulemaking obligations and found that the agency had not supported certification with the adequate factual basis as required in the act.

I want to make a point about this, too. DHS's reasoning if left unchallenged would have set a very dangerous precedent. Consider how that same logic, that the underlying obligation of the employer is not changed by obligation, could be applied by other agencies such as OSHA. The Occupational Safety and Health Act mandates that employers provide a workplace, quote, free from recognized hazards that are causing or are likely to cause death or serious physical harm. All of OSHA's regulations are merely detailed examples of these hazards and how employers must protect their em-

ployees from them. If OSHA was to adapt DHS' logic that any regulation did not change the underlying obligation of the employer, the agency would never have to determine the impact of a proposed regulation on small businesses and therefore would never conduct a SBREFA panel review taking input from actual small businesses and never have to produce small entity compliance guides, the requirements for which were recently enhanced in the minimum wage package passed earlier in the session.

Against this backdrop, the Chamber believes making the RFA as effective as possible is imperative. While we are often associated with our large members, the truth is that 96 percent of U.S. Chamber members are actually small businesses with 100 employees or less. As we have already heard this morning, everyone acknowledges that regulations impact small businesses more harshly than large businesses. If we are serious about keeping our small businesses competitive with global competition, we must make sure this act has the impact Congress intended when it passed it more than 25 years ago and then amended it with SBREFA in 1996.

Your bill would make several important improvements to the Regulatory Flexibility Act. Perhaps the most significant is requiring agencies to consider the indirect impact of regulations when calculating the impact of regulations on small businesses. We have heard about this a lot already this morning.

Let me just point out that that is particularly helpful with respect to the EPA regulations where the agency claims that because their regulations are actually enforced by the States, these regulations only have an indirect impact and therefore do not trigger the full range of RFA activities. Another important problem your bill addresses is improving agency compliance with section 610, the provision that requires agencies to review the regulations after 10 years. Your bill makes clear that the agency is to determine whether the regulation has a significant economic impact on a substantial number of small entities at the time of the review. The Government Accountability Office concluded that the original text of the legislation was not clear whether this impact applied to the time the regulation was issued or when it was being reviewed. This confusion has allowed agencies to legitimately claim that they were unsure how to proceed. Indeed, the Government Accountability Office has done quite a few studies on the Regulatory Flexibility Act, showing how agencies have failed to comply with it and repeatedly citing lack of clarity in the law's terms as a key reason.

One quote that I was able to uncover from the testimony says that GAO's reports indicate that the full promise of RFA may never be realized until Congress revisits and clarifies elements of the act, especially its key terms, or provides an agency or office with clear authority and responsibility to do so. They go on to point out that there is a domino effect that if an agency's initial determination of whether RFA is applicable to rulemaking has on the other statutory requirements such as the compliance guide and the periodic reviewing of regulations.

Madam Chair, I agree with the GAO that if we are serious about improving the Regulatory Flexibility Act, the most important thing would be for Congress to make clear what it means by the key term "significant economic impact" and "substantial number of"

small entities." These two phrases drive the overall question of whether an agency must apply the RFA to any given regulation. The agencies have taken maximum advantage of the flexibility in the Regulatory Flexibility Act to define these terms differently as they choose for any given regulation, with the goal being that the regulation is regarded as not having the subtle impact and thus avoid having to complete the requirements of the RFA. While these two terms cannot be defined the same for all regulations or even for all regulations within a specific agency, it is possible to establish the parameters and the elements that must be considered. Doing so would not only help agencies apply the RFA more consistently, it would also set benchmarks so that those of us who monitor agencies' compliance with the RFA would have some way to tell if they had done what they were supposed to do.

As we have heard already, one way to accomplish the goal would be to authorize the Chief Counsel of Advocacy to promulgate a rule-making defining these terms along with other requirements of agency compliance with the RFA. And as we have also heard, this idea has been included in legislation previously, most recently H.R. 682 through the Regulatory Flexibility Act, and I might add also by Senator Bond back in the 107th Congress in a bill he introduced call the Agency Accountability Act.

In the alternative, Congress could specify what it meant by these key terms and instruct agencies that they are to incorporate these elements as they apply these terms to the regulations. One other suggestion I would like to offer the committee is that for those regulations when an agency's certification is still not adequately supported, I think it would be most helpful to permit the judicial review of an agency's certification decision at a time closer to when that decision is made rather than the current law, which says you have to wait until the regulation goes final to bring your judicial review. This would preserve the ability of small businesses to get their input into the rulemaking at a time when it can still have an impact.

An excellent example of where this would have been particularly helpful is the recent case brought by the Aeronautical Repair Station Association, ARSA, for purposes of conversation, against the Federal Aviation Administration's regulation requiring contractors and subcontractors at any tier to establish mandatory drug and alcohol testing programs for employees performing maintenance functions in the aviation industry.

Chairwoman VELAZQUEZ. Mr. Freedman—

Mr. FREEDMAN. I am sorry.

Chairwoman VELÁZQUEZ. Your time is up. So maybe during the question and answer period you will be able to make any other—

Mr. FREEDMAN. By all means. Forgive me, Madam Chairwoman. Just let me say we look forward to helping you move this bill.

[The prepared statement of Mr. Freedman may be found in the Appendix on page 44.]

Chairwoman VELÁZQUEZ. Thank you. Thank you very much. Our next witness, Mr. Dyke Messinger, is the President and CEO of Power Curbers, Inc. He is testifying on behalf of the National Association of Manufacturers. Founded in Salisbury, North Carolina, Power Curbers sells products across the globe in more than 70

countries. The National Association of Manufacturers represents multinational firms, small and medium manufacturers, and 350 allied associations throughout the country. Welcome, sir.

**STATEMENT OF DYKE MESSINGER, PRESIDENT AND CEO,  
POWER CURBERS, INC. ON BEHALF OF THE NATIONAL ASSO-  
CIATION OF MANUFACTURERS**

Mr. MESSINGER. Thank you, Chairwoman Velázquez. It is a pleasure to be here. Ranking Member Chabot and Congressman Akin, it is a pleasure to see you, sir. I want to thank you for giving me the opportunity to talk about the Regulatory Flexibility Act.

As you know, NAM is the largest trade association representing large and immediate—small and medium manufacturers in all 50 States. Just another note about my business. We make mechanized construction equipment for paving concrete roads and curbs and sidewalks. We employ 104 people in North Carolina, Iowa, and Tennessee, and we sell our equipment in over 80 countries, and I am also a board member of a National Association of Manufacturers. I won't repeat the statistics that have been shared with the committee before about the report by Mark Crain for the SBA on the cost of regulation, but I will share some data on manufacturing.

In manufacturing, the disparity between large and small firms was the widest. The cost per employee for the smallest firms was over \$21,000, or over 150 percent higher than the over \$8,700 cost per employee for the largest firms.

In 2006, the NAM released an update to its report on how U.S. structural costs hurt our competitiveness in this country. It examined structural costs borne by manufacturers in the United States compared to our nine largest trading partners. The principal finding was that structural costs were almost 32 percent higher in the U.S. than for our foreign competitors. The structural costs included a regulatory compliance, corporate taxation, health and pension benefits, litigation and rising energy costs.

As a result, we welcome the leadership, Chairwoman Velázquez, and of this Congress in making improvements to the RFA. Our review of your proposed legislation leads us to conclude that your improvements to the RFA are sound and the NAM and its members are supportive of your efforts.

First, let me do emphasize you need to include the indirect economic effects in a regulatory flexibility analysis. A timely example of agencies not being able to consider the impact that they are truly having on small businesses is the EPA's national ambient air quality standards for ozone. Because the implementation of NAAQ standards is done through the regulation and approval of State implementation plans, there are said to be no direct effects on small entities because States are not small entities. Well, this is clearly contrary to what Congress intended when it passed the RFA. Periodic review of legislation, section 610, has always been an underperforming provision of the RFA. There is great hope that it would rationally reduce or eliminate some of the burdens on small businesses that had outlived their usefulness.

Let me give you an example. Many of our members and businesses across this country use aerial work platforms or cherry pickers. They also use scissor lifts in their facilities to perform mainte-

nance or to do a specific task. Well, there are fall protection standards that are very important that are attached to these devices. After all, putting somebody up in the air so many feet from the ground is important. The regulation—some of the regulations for these are 30 years old and they don't apply separately to each machine. So that you don't—depending on which machine arrives in your facility, you have different regulations. You don't know what to comply with and of course when OSHA comes in and takes a look, they are going to tick off what you did or didn't do.

So that is something that I have noted in my business and the people that bring this equipment in don't really understand the OSHA regulations. They are there to execute a piece of work. So we believe that enhanced reporting requirements will create the necessary environment for better retrospective review.

There are also circumstances where an individual rule is not particularly burdensome or a challenge to many small business, but the cumulative effect of that rule and many others affecting a particular sector or type of business can be crushing. Cumulative effects are not always easy to quantify, but the current loophole of providing this analysis, quote, to the extent practicable, gives agencies too large of an opportunity to walk away from this responsibility and the use of, quote, where feasible, unquote, is a limitation to the review of the number of small entities affected seriously weakens the requirement. Changes to this limiting language in several parts of the RFA will go a long way to improving agency compliance and analysis.

The NAM was also supportive of former Chairman Manzullo's H.R. 682 in the previous Congress. We believe there are a few provisions of that bill that would strengthen your legislation, and I have included those suggestions in my prepared testimony.

Thank you again, Madam Chairwoman, for this opportunity to testify.

Chairwoman VELÁZQUEZ. Thank you, Mr. Messinger.

[The prepared statement of Mr. Messinger may be found in the Appendix on page 53.]

Chairwoman VELÁZQUEZ. Our next witness is Mr. Andrew Langer, he's the senior manager of the regulatory affairs at the National Federation of Independent Businesses. Prior to joining NFIB, he was associate director of the development for the Competitive Enterprise Institute. The National Federation of Independent Business represents over 600,000 small businesses before Congress and all 50 States. Thank you and welcome.

**STATEMENT OF MR. ANDREW LANGER, SENIOR MANAGER, REGULATORY AFFAIRS, NATIONAL FEDERATION OF INDEPENDENT BUSINESSES**

Mr. LANGER. Thank you very much, Chairwoman Velázquez, Ranking Member Chabot and Congressman Akin. Thank you very much for allowing me the opportunity to testify here today on behalf of the hundreds of thousands of small businesses owners represented by NFIB.

I am happy to be here to discuss with you the burden of regulatory paperwork and to offer our insights on how to find a way to reduce the amount of paperwork filled out by America's small busi-

nesses each year. I attended your hearing on regulatory burden several weeks ago and I really appreciate the invitation to come here and discuss these burdens in greater detail. NFIB is the Nation's largest small business association, and it is fairly unique amongst trade associations in Washington D.C.

NFIB represents truly small businesses. Ninety percent of our members have fewer than 20 employees and our average member size is 10 employees. I know we have discussed at great detail the difference between small and large businesses here, and I won't restate those issues here today. But if there is any message I hope to convey today, it is that agencies cannot create regulations in a vacuum. Agencies have to take into account how each and every little rule adds up to literally weeks worth of a small business's time. We must consider what I have taken to calling the context of regulation.

We spent a tremendous amount of time focusing on the big picture, and the big picture of regulatory burdens is important, it sets out the most general context in which to consider the problem of regulatory burdens. As Tom Sullivan said, our regulatory State costs over a trillion dollars annually. Americans spent 8 billion hours, billion with a B, filling out paperwork last year at a cost of over \$400 billion. These are vast figures, they are almost too large for any person to really comprehend.

Let me put it to you this way: For an adult population of 210 million people, that is 210 million people over the age of 18 in America, that is 38 hours for every adult. Almost the equivalent of a workweek's worth of time spent filling out paperwork for the Federal Government. This is what I mean by context, the assessment of each rule's individual impact and how that impact adds to the Agency's current regulatory burden, taken by itself a rule might create very little burden.

For example, in a hearing last year on a proposed EPA regulation on home renovation, a lot of talk focused on a mandate requiring agency training of 1 day, per quarter, per employee. Many people dismissed this as a simple request, what is 1 day every 3 or 4 months after all. But that is 3 or 4 days per employee, per year, and this is on top of all the other training, paperwork and other regulatory burdens that a small business and those employees might be required to jump through.

We believe at NFIB that the agencies ought to keep track of each of those mandates, quantifying them and adding them up each and every year. And then when new regulations are proposed, calculate the burdens being added and then restate the overall burden being opposed by the agency. It is really only in this way that we can really assess what is being added and consider whether or not such additions are necessary and in that framework.

And in context cuts both ways as well, understanding that it isn't a single regulation that creates this burden, but thousands of them underscores the necessity for not only making incremental changes to the regulatory state, but supporting the agencies when they do so as well. When EPA comes out with a regulatory change that reduces the burden on small business of 15 hours, we can't dismiss that. Fifteen hours is 2 days, 2 days here and 2 days there over the thousands of regulations that are on the books, and pretty soon

you are talking about real time. Time, after all, is a small business's most precious and most finite resource.

We also believe that accountability and transparency are important, and we believe that these two concepts can be effectively joined with the efforts to reduce regulatory burdens that gets to what Congressman Gonzalez was talking about before. In addition to our recommendations on regulatory compliance guides, we believe that all regulations and their associated documents should have a name and direct dial phone number of the regulation's principal author attached. Some might balk at this, but we believe that it gets to the heart of government responsiveness.

One of the most problematic parts of figuring out how to be in compliance with regulations is getting answers to basic questions about them. Rarely do single agency points of contact have the detailed knowledge about a particular regulation to actually provide the meaningful information necessary.

And small business owners spend countless hours working their way through agency offices in order to find the right person to answer their question. But who better really to answer a question about a regulation than the person in the agency who is responsible for bringing that regulation through the promulgation process? Moreover, if an agency employee is required to attach his or her name to a regulation, we believe that more care might be taken to ensure that a regulation is as clear as possible and doesn't burden small business any more than it has to.

Thank you, again, for the opportunity to testify. In our written remarks we have offered a series of 10 separate recommendations, several of which have been adopted and included in your legislation. We look forward to working with you and answering any questions that you might have.

Chairwoman VELÁZQUEZ. Thank you, Mr. Langer.

[The prepared statement of Mr. Langer may be found in the Appendix on page 60.]

Chairwoman VELÁZQUEZ. Welcome again, Mr. Charlie Sewell. He is the senior vice president of government affairs at the National Community Pharmacists Association. Prior to joining, NCPA, he was the president of ACG Enterprises. National Community Pharmacist Association represents 24,000 independent pharmacists and 50,000 community pharmacists and their patients across the country, welcome.

**STATEMENT OF MR. CHARLIE SEWELL, SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION**

Mr. SEWELL. Thank you, Madam Chair, and thank you Ranking Member Chabot and the other members of the committee for having us here today. I would like to say that we still represent 24,000 pharmacies, but actually we only represent 23,000 pharmacies now because we lost 1,152 pharmacies in the last year because we got a new business partner, with the advent of Part D we now have Uncle Sam as a business partner and we found out he's not a very good business partner as said before. That is why we are happy to be here today.

Most importantly, we represent not only the 23,000 pharmacies, and their over 300,000 employees, but millions of patients that we serve day in and day out. We help them in terms of improving their adherence to their drug regimens. We help them avoid adverse drug interactions, we even provide home delivery for free in most of our pharmacies, which is almost unheard of in this day and time. It is really because of our face-to-face relationship with a local independent pharmacy that patients are more likely to take medicines on time and more likely to take them properly and more likely to refill their meds when they need to.

And frankly, more likely to get the care that they need because we spend more time with most of our patients than their doctors do, especially in rural America and the urban centers. We are happy to be here today to say that we strongly support the small business Regulatory Improvement Act. It is much needed, long overdue, and the sooner the better from our perspective.

We would ask, though, that actually you consider strengthening it even more. Specifically we would recommend that no agency can issue a final regulation unless it specifically analyzes the significant impact that implementation of the rule will have on small business. Agencies shouldn't be allowed to hide behind lack of evidence which is what they always cite.

In order to proceed, agencies must affirmatively demonstrate that there is no significant adverse impact on small businesses. Secondly, once there is a finding of significant impact upon small business, an agency should not be allowed to implement a rule for the small business sector that it affects. And lastly, a private person or any entity or any government entity for that matter once a rule is released, that person or entity should be able to bring up a regulatory challenge when they believe there has been a violation of the RFA, and frankly, what we would like to see is an SBA process created where that action could be adjudicated in a fairly efficient manner and fairly expedited manner by the SBA.

I want to cite one specific example that we have talked about before that really is really our major concern, that is a recent rule that was promulgated by CMS. The GAO did a study and said that under the new Medicaid reimbursement proposal we would be reimbursed 36 percent below our cost. The OIG did a study and said that from 19 of the 25 drugs that they examined we would be reimbursed below our cost. If you take into account that you actually have to pay the pharmacists who work in our pharmacies, you actually have to pay a rent or a mortgage, you actually have to pay for the utilities, 24 of the 25 drugs they examined we would be losing money on, it really is a horrendous situation.

When it came time to perform the regulatory flexibility analysis in their final rule, frankly they said, we are going to ignore the GAO findings, we are going to ignore the OIG findings and then they told us that we need to provide more documented evidence. We actually used SBA standards and we showed them directly that we would lose, our net margins would sink to the tune of about 80 percent, when you are only make 2.6 percent net margin to begin with, almost 80 percent reduction in that margin doesn't work, it just don't keep us in business.

We can't believe that CMS totally neglected the RFA in the fashion that they did. Something needs to be done. The more teeth that we can put to the RFA the better. Agencies need to be required to actually do real economic analysis, and when there is significant impact, they have to actually stop what they are doing before they promulgate the rule. They certainly need to take into account the small business sectors that will be impacted. Thank you very much, Madam Chair.

[The prepared statement of Mr. Sewell may be found in the Appendix on page 75.]

Chairwoman VELÁZQUEZ. Thank you. I would like to address my first question to Mr. Freedman. And you spoke about the fact that the Regulatory Flexibility Act does not define significant economic impact and, in fact, the Government Accountability Office concluded that the lack of clarity regarding this term has reduced the effectiveness of the law. And also courts have ruled that agencies did not have to consider the indirect impact of a rule on small businesses. The legislation we are examining today requires agencies to contemplate reasonably foreseeable indirect economic impacts.

How will this improve the regulatory process for small businesses and will it result in a more accurate assessment of the two economic impacts on small businesses?

Mr. FREEDMAN. Thank you, Madam Chairwoman, for the question. I think you actually hit one of the several nails on the head, the indirect impact, as I have mentioned, and as others have discussed, is one of the ways that agencies avoid taking into account certain impacts on small businesses. The aeronautical repair station case I was about to mention, I think, brings that out very clearly. The FAA said that the impacts were merely on contractors, and therefore, not direct impacts. The court found differently and said that these impacts, in fact, should be included.

I think the indirect impact question has been one of those holy grails in the pursuit of better reg flex compliance. Your legislation, I think, does a very good job of trying to capture the levels of indirect impact. I think that is where the debate lies.

You talk about reasonably foreseeable. That is about, I think, as good a line as one can draw around this. Let us be honest, I think that will trigger litigation, but you do have to draw a line and I think that is a good way to draw that line. So basically, the answer to your question is yes, it would help greatly and it would definitely make a difference in a lot of regulations in terms of the impacts that have been discussed this morning and in other iterations that we all have dealt with.

Chairwoman VELÁZQUEZ. Mr. Langer, would you like to comment?

Mr. LANGER. Well, no. I have no disagreement with Marc on this. I like to think of the regulatory State as almost an organic creature, and that you make a change somewhere it will have a ripple effects down the road and effect other things. Industries in our economy are not independent entities, they are all interconnected in many ways. And so when government makes a change somewhere it is going to have an impact down the road and sometimes very serious and very problematic ones.

I think Chief Counsel Sullivan underscored a great one when he was talking about the hemispheric travel restrictions issue and the impacts that is going to have industry wide in multiple industries and how that wasn't taken into account. I think that is one of the great problems we will run into.

The greatest growth in regulation is happening in Homeland Security and we are seeing all sorts of impacts down the road for things that DHS simply isn't contemplating.

Chairwoman VELÁZQUEZ. Thank you.

Mr. Messinger, I understand that the disparity on regulatory costs between large and small businesses is widest in the manufacturing sector, can you talk to us about how certain regulations or agencies do more to address the unique concern? They could do more to address the unique concerns of a small business manufacturer and do you hire legal consultants to assist in compliance?

Mr. MESSINGER. Yes, we hire legal consultants to help us when needed. It is not on retainer or anything, we just use them when we need them, but quite frequently we do. I don't know if I can comment on specific agency regulations. I have to check with my staff. What I do know is what we have all said is just the cumulative burden of the variety of things we are asked to do makes it where you sit down and look at this stuff and you say, of what real need and use does this have? We can all appreciate the need for a clean environment, for safe working conditions and those sorts of things, but when it appears to be paperwork, appears, then people begin to distrust the system and that is what we don't want to have happen.

Mr. LANGER. Congresswoman, if I could just add to that, because there are some good examples that are out there, OSHA in the last few years has taken a particularly different approach—the Department of Labor itself has taken a different approach in many ways in dealing with small business and working closely with a number of entities out there.

OSHA has developed what they call their OSHA consultation process, which we have been invested in for some time where they will go out and they will provide expertise to come into businesses, to not inspect but assess and then offer recommendations as to how they might improve their workplace safety and health programs. A number of entities out there a number of insurance companies are offering incentives to the small businesses that partake in that program and get certified and small businesses are saving money while protecting their employees. So that is one I would recommend.

Chairwoman VELÁZQUEZ. Mr. Sewell, let us talk about the AMP rule, CMS did not consider any alternatives to minimize the impact of the rule on small businesses, instead they concluded that out of State did not require it to examine any other alternatives. Can you talk to us, do you have any alternatives or ways to implement the rule that will be less burdensome to community pharmacists?

Mr. SEWELL. We have made recommendations and there is legislation being considered both here in the House and Senate at the moment to address this. We are afraid given the congressional calendar, it will be difficult to make anything happen this year.

So the latest discussion with Senator Baucus and now Mr. Stark here in the House is in regards to a delay, the hope is that they would at least delay until people would see the AMP data. When we submitted our comments to CMS, they never give us the AMP data, so it was impossible for us to comment on the specific harm. The only two entities that actually received the data were OIG and GAO and they are the ones who came up with the number showing that we will be reimbursed below cost. CMS criticized us for not offering specific comments, but yet wouldn't provide us the data. They have still not provided the data to Congress. We don't see how they can go forward with this rule when no one has the data, including the Congress.

Chairwoman VELÁZQUEZ. Another issue related to CMS is the Medicaid generic prescription drug reimbursement rule and its impact again on small pharmacists. Why do small pharmacists face a particular severe economic impact from this rule compared to larger counterparts and what are the consequences from community pharmacists if this new formula is implemented?

Mr. SEWELL. The average Medicaid business that an independent pharmacy does is 14 percent of their total business, for chain pharmacies it is about 7 percent, so twice as much business. We have over 10 percent of our pharmacies, or about 2,300 pharmacies, over 50 percent of their business is Medicaid. If this goes through, those 23 pharmacies will close almost overnight. We have been in constant contact with our members, and that is what they have told us, there is just no way they can stay in business. Any pharmacy with a disproportionate share of Medicaid business is going to be in trouble, and most Medicare business tends to be concentrated in rural and the urban centers, and that is where most independent pharmacies are located.

Chairwoman VELÁZQUEZ. Mr. Chabot.

Mr. CHABOT. Thank you very much, Madam Chair. I first want to commend the panel for something, all four of you have done your homework, you pronounced my name correctly, all four of you. That is the first time that has happened all year. When I first ran for office back in 1979 so it has been 28 years ago, I ran for Cincinnati city council as an independent, didn't have much money so we had a 10 second ad and that is all we could afford. And so we had my yard sign on there, it just said Chabot, and we had a woman's voice and a man's voice and it kind of went back and forth. And one said, Chabot, one said Chabot, Chabot, Cabot. And then the voice over said, although nobody agrees on how to pronounce his name, everybody agrees he will make a fine city council. That was our ad and we lost. We finally did win, but it was a few years later, but in any event, thank you for that, not that I really care how you pronounce my name, but in any event we do pronounce it Chabot. It is a French name, most French men pronounce it Chabot.

We will begin with you Mr. Freedman, if I can. Agency determinations of no significant impact at the proposed rule stage are not currently reviewable. If such decisions were reviewable, would this not undermine the ability of the agency to learn from the rule-making process and correct its mistakes, the overarching premise of notice and comment rule making?

Mr. FREEDMAN. Thank you, Mr. Ranking Member. I guess my feeling there is that I would rather see an agency get it right the first time and get an analysis out that makes sense and covers all the various factors that need to be included, rather than rely on a rule-making process, which my experience is while there are changes that are possible in a rule-making process, when you see the proposed rule, you are seeing what the agency wants to put out. As I like to say, it may not be carved in stone, but the concrete is wet. And so I would rather them get it right the first time than to have to rely on a comment process to correct them.

Mr. CHABOT. Mr. Messinger, given the fact that your company already has sunk significant capital costs into complying with existing regulations, is it more important to focus on preventing new burdensome regulations or eliminate existing burdensome regulations?

Mr. MESSINGER. Can we work on both?

Mr. CHABOT. Good suggestion, yeah.

Mr. MESSINGER. I guess it would depend on what the issue is, but surely you have to stop or slow down the unnecessary new regulations, but we just got a field of issues to deal with today. I don't know, that would be tough, but I would leave it up to those that are involved in the details of those issues a little more. I guess if I had to pick, it would be the existing regulations.

Mr. CHABOT. Thank you.

Mr. Langer, even if an agency does not enumerate cumulative impacts, should the cumulative impact of regulations be taken into account when an agency makes the threshold decision of whether to perform an initial regulatory flexibility analysis.

Mr. LANGER. I think it has to. I mean, the problem is right now we have a situation where when we assess regulatory burdens in the case of garbage in, garbage out, the executive branch understate regulatory costs consistently, they underestimate cumulative regulatory costs vastly. If we were to go only on the basis of what the Office of Information & Regulatory Affairs and don't get me wrong, I have nothing but respect for Director Dudley and the work that she is doing over at OIRA, but annually, we, get this reporting of the costs and benefits of regulations and the State that cost and regulations are up \$44 billion. We know that is not the case. They are looking at a dozen rules.

And so the agencies have to do a better job if they are not going to assess the incremental costs, they have to do a better job at assessing their overall costs. We need to get a better handle on this because there is a fundamental misunderstanding of just what the burdens are. We are looking at a regulatory burden which roughly equals the entire Federal budget, and that just is an unsustainable situation for American business.

Mr. CHABOT. Thank you.

Mr. Sewell, in your opinion, does FDA accurately assess the economic consequences of its regulatory issuances of small pharmacies and suppliers?

Mr. SEWELL. In a word, no. I will give you a specific example, right now they are considering imposing track and trace technology, something that we support to protect the drug supply from manufacturer all the way down to the pharmacy level. However,

the cost of this technology could be anywhere between 10 and \$40,000, that is a lot of money for a small business. That would be an unfunded mandate that would be basically placed on the back of pharmacies. And that is not taking into account the time to actually do track and trace technology, that is to track and trace the individual drugs. In fact, some of the discussions as we understand it would be looking at a situation where it would be almost as cumbersome as tax compliance, it could take an extraordinary amount of time. So the answer in a word is no.

Mr. CHABOT. Thank you, very much. Madam Chair, I yield back the balance of my time.

Chairwoman VELÁZQUEZ. Mr. Ellsworth.

Mr. ELLSWORTH. Thank you, Madam Chairwoman. I just have to tell you, I have been practicing the ranking member's name and for a year now, and now that he has given me those others options, I have forgotten how to pronounce it. So if I say Chabot, I apologize. I had Chabot down, there it is again.

Gentlemen, thank you very much. I appreciate you being here, I could ask you questions all day. I appreciate you being here. First, if you don't mind, in what we are talking about today, if the chairwoman had the magic wand and was giving away Christmas presents today and you had one thing you could say, I walked out of there and I won this for my constituents, could you go down the line and tell me what that would be if you walked out today and got it done?

Mr. FREEDMAN. That is a hard question, I guess I would probably point to the indirect impact in language in the bill. If you are talking about one specific provision, other than just saying I walked out of here and got the bill done, I would focus on indirect impact language in the bill. I think that was the one that would probably make the greatest impact on the regulatory process.

Mr. ELLSWORTH. Mr. Messinger.

Mr. MESSINGER. I am not schooled in the legislation, I am a businessman.

Mr. ELLSWORTH. One thing that would make your life easier as a businessman that this committee could do.

Mr. MESSINGER. Well, Mr. Langer talked about how OSHA has really done some good things and become more responsive. I think if we could apply that to EPA, I think this country has become more green, certainly this last year we have seen that. I think people in government don't realize that all Americans, most Americans are very supportive of what we need to do to have a sustainable future, but the EPA's regulations on smaller businesses are terribly burdensome, I don't want to get into that, but I would move in that area.

Mr. LANGER. If the chairwoman has already given Marc his present of indirect impacts, I get a different one. I will keep hammering on the issue of phone numbers of the agency personnel, the principal office of regulations. I know it may sound gimmicky, but I think, frankly, down the road it could have a sea change effect. I mean, every time I talk to my members, I talk to our field personnel, I talk to folks who deal with the regulated entities, they look at me like, boy, that is an interesting idea. The idea that you can actually pick up and call the person who wrote the regulation.

So if Marc is already getting direct impacts, I will go with the phone number issue.

Mr. SEWELL. Certainly indirect impact is important to us as well, but we would like to add that we would like to be able to make regulatory challenges to go through an abbreviated process and be adjudicated by the SBA, we think that would really make a big difference.

Mr. ELLSWORTH. Thank you very much.

Mr. Freedman, I notice that the SBA releases a report grading the agencies on their responsiveness on regulatory fairness, compliance, and I love the word that some identified as suboptimal, I am guessing there are other words for that.

Mr. FREEDMAN. One wonders what Chairman Greenspan would have to say about the regulatory world.

Mr. ELLSWORTH. Right. But suboptimal, I will use that word, I can think of others, Department of Ag, Defense, Justice, Education, Treasury. In your work with small business, are any of our other departments doing well above optimal, or let us just say optimal.

Mr. FREEDMAN. Actually, that is a fair question, I think in constant refrains about what needs to be done to improve the regulatory flexibility, we do tend to overlook where agencies have made, I guess, at least a conscientious effort, in some cases, hit the mark.

I would cite too, it is ironic because we keep sort of discussing it in negative terms, but EPA, I think, does a very conscientious effort at trying to assess the impacts. Now, in a number of cases, I don't think they get all the impacts in there that they should have. But I do know they have a matrix that they work from in terms of what level of impact is considered significant and how to assess the number of small entities.

So I am not going to give them the pat, but I will cite them as an agency that does more on this than other agencies.

Similarly, I think OSHA has, over the years, done a much better job at making sure that they capture those impacts and do what they are supposed to do. Now again, I am not going to say that they always get it right, but they do recognize the burden and go through the process more contentiously than others.

Mr. ELLSWORTH. Mr. Langer, I think if I remember correctly in your testimony, you talked about the burden of paperwork, how it continues to grow. Which one has caused you the most angst to you and your members, are there ones that just are most costly and cause the most angst.

Mr. LANGER. Well, it is well documented that tax paperwork is the biggest burden out there. It is 80 percent of the paperwork burden that anybody faces. Part of the problem is complexity of the code. We can get into the difference between beneficial paperwork and non beneficial paperwork and the benefits that accrue from it. Really, with paperwork overall, it gets back to my earlier point, which is it is all incremental, it is never one big regulation that is out there; we are always looking for magic bullets, and there is no magic bullet here. It is 15 minutes here, the 2 hours here, 3 hours there, it all adds up to literally a week's worth of time for every adult American.

Mr. FREEDMAN. If I could just add. These regulations don't happen in a vacuum as we have heard. The thing I think about is the

people who have to deal with these, small business owners, yes, their businesses are affected, but it is also a matter of their private lives and the time that they would be spending time outside of their business. The people I think about have multiple roles within that business and adding more regulatory complexities to those roles means that is less time they have to do other things that we all think about in terms of family life and work outside of business.

Mr. LANGER. See, that is why I think these incremental costs are so important to assess and get a handle on. Because if the agent is already requiring a small business owner to spend a week of paperwork, adding more days, it is very serious stuff here. So annually, at the end of the year, the EPA could come back and say, we have added an hour of paperwork for everybody, or we have subtracted a few hours. Across the board, you start whittling away at it and you are really getting somewhere.

Mr. ELLSWORTH. Thank you very much. I yield back, Madam Chair.

Chairwoman VELÁZQUEZ. Mr. Chabot.

Mr. CHABOT. No.

Chairwoman VELÁZQUEZ. With that we conclude this hearing. And again, I want to thank all of you for your time here and for your contribution to this important issue for small businesses. I ask unanimous consent that members will have 5 days to submit a statement and supporting materials for the record. Without objection so ordered, this hearing is now adjourned.

[Whereupon, at 12:05 p.m., the committee was adjourned.]

**STATEMENT**

Of the Honorable Nydia M. Velázquez, Chairwoman  
United States House of Representatives, Committee on Small Business  
Full Committee Hearing: "Legislation to Improve the Regulatory Flexibility Act"  
Thursday, December 6, 2007 at 10:00 am

I call this hearing to order to address "Legislation to Improve the Regulatory Flexibility Act."

Today, the Committee is reviewing legislation to strengthen the Regulatory Flexibility Act, or RegFlex. Passed into law in 1980, RegFlex has played a critical role in ensuring that America's small businesses are not overly burdened by federal regulations. While the Act has improved this process in many ways, small firms are still more affected by regulations than are their larger counterparts.

The reality is that more must be done to address this problem that can hurt our overall economy.

Last month, this Committee took the first step in identifying ways to improve RegFlex. We heard from small businesses representing a diverse group of industries on ways to craft legislation to strengthen the Act.

There was one clear theme present in the testimony: Agencies are not doing enough to consider the impacts of their rules and regulations on small businesses. A more effective statute can help reduce unnecessarily burdensome regulations.

Working with the minority, the small business community, and with input from the SBA Office of Advocacy, the Committee has written draft legislation which addresses a number of the deficiencies of RegFlex.

One of the goals of the legislation is to address the problem of outdated regulations. The Committee Print would clarify when agencies need to review specific rules. It also gives small businesses a greater voice in the process and enhances transparency, helping to eliminate unnecessary burdens.

The committee also wants to ensure that agencies are not ignoring the underlying requirements of RegFlex. The Act was never intended to completely eliminate or slow down regulations, but for agencies to consider if there are more effective alternatives to meet policy goals. Too often, agencies avoid fully analyzing the impact of their rules on small businesses by certifying that a rule will have no significant consequences.

This bill will strengthen the analysis requirements by compelling agencies to consider reasonably foreseeable indirect economic impacts on small businesses when writing rules.

One key recommendation from the Office of Advocacy was to codify Executive Order 13272, which is included in the legislation. This change puts in statute that there must be greater coordination between agencies and the SBA Office of Advocacy, ensuring that regulators fully consider the economic impacts on small firms. Earlier notification will provide Advocacy with a greater opportunity to assist agencies in RegFlex compliance.

This print we are reviewing today is by no means a final version. Today's panelists will discuss how this language can help small businesses and identify ways it can be improved. I would like to thank all of the witnesses today for coming to the Committee and sharing their views.

I look forward to continuing our work with Ranking Member Chabot to pass meaningful reform to the Regulatory Flexibility Act which will lessen burdens on small businesses and allow our nation's entrepreneurs to continue to move our economy forward.

**U.S. House of Representatives  
SMALL BUSINESS COMMITTEE**

Representative Steve Chabot, Republican Leader

Thursday,  
December 6, 2007

**Opening Statement of Ranking Member Steve Chabot**

*Legislative Hearing on the Regulatory Flexibility Act*

"I would like to thank the Chairwoman for holding this hearing on legislation to strengthen the Regulatory Flexibility Act.

"New small businesses open every year. Buffeted by a variety of economic and financial hardships, these businesses struggle mightily to achieve a profitable bottom line. Small businesses are particularly affected by unnecessary and burdensome regulations that require more money and time than their larger competitors to adequately comply. Small businesses, according to a study by the Office of Advocacy of the United States Small Business Administration, pay \$2,000 more per employee per year than large businesses to comply with the tornado of federal regulation. In some sectors, such as manufacturing, the per-employee cost is even higher than that average. The unfortunate, but expected, result is hundreds of thousands of small businesses are forced to shut their doors.

"More than 25 years ago, Congress recognized there was a regulatory storm brewing and smartly reacted with legislation to force federal regulators to examine the impact that their rules will have on small businesses before inadvertently putting them out of business. Congress' answer to the regulatory problem was called the Regulatory Flexibility Act.

"Enactment of the RFA forced a small but perceptible shift in the tack of federal regulation. While some agencies were prompted to refocus their thinking and develop less burdensome regulation, many others treated the RFA as merely suggestion and were undeterred on their course for more and more burdensome and overlapping regulation.

"Congress attempted to strengthen the RFA in 1996 by enacting the Small Business Regulatory Enforcement Fairness Act. The act made agency compliance with the procedural requirements of the RFA judicially reviewable independent of any challenge to the underlying agency rule. With the threat of litigation hanging over them, federal agencies began paying more attention to the RFA, but the added attention did little to increase cooperation from many agencies.

"The valiant efforts of Dr. John Graham and Mr. Tom Sullivan, one of our witnesses today, attempted to tame the tidal wave of federal bureaucracy. And while they admirably eliminated many problems in the system, we have not seen the dramatic change small businesses require, as evidenced by many small firm owners that have come before this Committee requesting help and by the many businesses forced to shut down each year.

"The efforts of Chief Counsel Sullivan have been hampered by the inadequacy of the RFA. Plagued by undefined terms and vague parameters, the RFA is far from an ideal statute. Existing loopholes permit agencies to circumvent the rules with negligible penalties.

"Last year, I cosponsored H.R. 682, a bill designed to significantly strengthen the RFA so that agencies – as President Bush stated – "will care that the law is on the books."

"The bill under consideration today adopts some of the changes that were in H.R. 682 by requiring agencies to consider indirect effects, to provide a more detailed assessment of the impacts, and to make the periodic review of

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"rules more transparent. These changes will help to ensure that small businesses need only endure necessary regulations and that agencies will not be able to create new ones to harm or destroy these businesses.

"Whenever Congress considers altering the RFA, opponents argue that changes would destroy the regulatory process or overwhelm federal courthouses. Examination of the Federal Register and courthouses show they remain strong despite the "supposed strength" of the RFA hurricane.

"Ultimately, what is at stake is the ability of small businesses to stay in business – based not on the whims and dictates of federal bureaucrats, but on their capacities in the marketplace. Better, sounder rules will be beneficial to the regulatory objectives of the agencies through increased compliance and lower costs to small businesses.

"No good reason exists to oppose the goals and objectives of this bill other than the fear of the unknown. I stand ready to work with Chairwoman to see that we get a much stronger version of the RFA.

"With that, I yield back."

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**Statement of Rep. Ellsworth****Hearing on: "Legislation to Improve the Regulatory Flexibility Act"****December 6, 2007**

Thank you Madam Chair. I want to take a moment to thank Chairwoman Velazquez and Ranking Member Chabot for holding this important hearing. This is an important issue for this Committee, and I look forward to hearing what these members of the small business community have to say about the draft bill before us today.

A few weeks ago, when we had our first hearing on the Regulatory Flexibility Act, it became clear that there are serious problems with the way the federal government is treating small businesses throughout this process. At the last hearing, the operator of a small trucking firm was here, and I asked him what kind of impact uniform federal regulations have had on his business. He told me it hurt his business and others like him. It was clear to him that big corporate trucking firms—with their teams of lawyers and compliance officers—have a leg up.

As we all know, the small companies in our districts are facing the same burden. The federal government has ignored the effects of regulations on small businesses and refused to adjust them to the needs of these vital employers. This is not a small problem: one million two hundred fifty thousand workers are employed by small businesses in Indiana. And, they deserve to have their voices heard. To bureaucrats in Washington, this may not seem like a problem. But, to Hoosier small businesses, it is. That's why I'm glad we're addressing this issue with the draft bill before us today. I look forward to hearing from today's witnesses and working with everyone in the future to make sure we solve this problem.

**CONGRESSWOMAN YVETTE D. CLARKE  
Statement Before the House Small Business Full Committee Hearing  
on Legislation to Improve the Regulatory Flexibility Act.**

**December 6, 2007**

Thank Madam Chair and Ranking Member Chabot for holding this hearing today to review legislation to improve the Regulatory Flexibility Act.

- There is no question the RegFlex needs to be strengthened.
- Agency compliance with many parts of the Act is of great concern and must be addressed immediately since most agencies currently view compliance as voluntary.
- I believe that we will develop solid provisions that will consider the indirect impact of regulations when calculating the impact of regulations on small businesses.



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*Advocacy: the voice of small business in government*

*Testimony of*

***The Honorable Thomas M. Sullivan  
Chief Counsel for Advocacy  
U.S. Small Business Administration***

***U.S. House of Representatives  
Committee on Small Business***

**Date:** December 6, 2007  
**Time:** 10:00 A.M.  
**Location:** Room 2360  
Rayburn House Office Building  
Washington, D.C.  
**Topic:** Legislation to Improve the Regulatory Flexibility Act

*Created by Congress in 1976, the Office of Advocacy of the U.S. Small Business Administration (SBA) is an independent voice for small business within the federal government. The Chief Counsel for Advocacy, who is appointed by the President and confirmed by the U.S. Senate, directs the office. The Chief Counsel advances the views, concerns, and interests of small business before Congress, the White House, federal agencies, federal courts, and state policy makers. Issues are identified through economic research, policy analyses, and small business outreach. The Chief Counsel's efforts are supported by offices in Washington, D.C., and by Regional Advocates. For more information about the Office of Advocacy, visit <http://www.sba.gov/advo>, or call (202) 205-6533.*

Chairwoman Velazquez, Ranking Member Chabot, Members of the Committee, good morning and thank you for the opportunity to appear before you today to address legislative improvements to the Regulatory Flexibility Act (RFA). My name is Thomas M. Sullivan and I am Chief Counsel for the Office of Advocacy at the U.S. Small Business Administration (SBA). As Chief Counsel for Advocacy, I am charged with monitoring federal agencies' compliance with the Regulatory Flexibility Act (RFA). Because the Office of Advocacy is an independent office within SBA, the views that I express do not necessarily reflect the views of the Administration or the U.S. Small Business Administration. This statement was not circulated to the Office of Management and Budget (OMB) for comment.

#### **Background of the RFA and the Small Business Regulatory Enforcement Fairness Act**

In 1980, Congress enacted the RFA after determining that uniform federal regulations produced a disproportionate adverse economic hardship on small entities. In order to minimize the burden of these regulations on small entities, the RFA mandates that federal agencies consider the potential economic impact of federal regulations on small entities. The RFA also requires agencies to examine regulatory alternatives that achieve the agencies' public policy goals while minimizing small entity impacts.

Agency compliance with the RFA, however, was not judicially reviewable. Since agencies could not be held legally accountable for their noncompliance with the statute, many agencies ignored the RFA and did not conduct full regulatory flexibility analyses in conjunction with their rulemakings.<sup>1</sup> In response, Congress amended the RFA in 1996 by enacting the Small Business Regulatory Enforcement Fairness Act (SBREFA), which provided for judicial review of agencies' final decisions under the RFA and added requirements for the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA).

The RFA requires agencies to prepare and publish an initial regulatory flexibility analysis (IRFA) when proposing a regulation, and a final regulatory flexibility analysis (FRFA) when issuing a final rule for each rule that may have a significant economic impact on a substantial number of small entities. The purpose of the analysis is to ensure that the agency has considered the economic impact of the regulation on small entities and that the agency has considered regulatory alternatives that would minimize the rule's economic impact on affected small entities. The RFA allows the head of an agency to certify a rule in lieu of preparing a regulatory flexibility analysis if the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Pursuant to the RFA, the agency must provide a factual basis for the certification.

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<sup>1</sup> The findings section of the Small Business Regulatory Fairness Act, states that "the requirements of chapter 6 of title 5 of the United States Code, have too often been ignored by government agencies, resulting in greater regulatory burdens on small entities than necessitated by statute." See, Section 202(5) of Public Law 104-121(1996).

### **Executive Order 13272**

Even with the additional requirements under SBREFA and the threat of judicial review, some agencies were not complying with the requirements of the RFA. On March 19, 2002, President George W. Bush announced his Small Business Agenda, which included the goal of “tearing down the regulatory barriers to job creation for small businesses and giving small business owners a voice in the complex and confusing federal regulatory process.” To accomplish this goal, the President sought to strengthen the Office of Advocacy and improve the success of RFA implementation by creating an executive order that would direct agencies to work with the Office of Advocacy early in the regulatory development process and properly consider the impact of their regulations on small entities. On August 13, 2002, the President signed Executive Order (E.O.) 13272, titled “Proper Consideration of Small Entities in Agency Rulemaking.”<sup>2</sup>

E.O. 13272 enhances Advocacy’s RFA mandate by directing Federal agencies to implement written procedures and policies for measuring the economic impact of their regulatory proposals on small entities. It also requires agencies to notify Advocacy of draft rules that are expected to have a significant economic impact on a substantial number of small entities and to give every appropriate consideration to any comments provided by Advocacy, including publishing a response to Advocacy’s comments in the *Federal Register*. The Office of Advocacy must provide periodic notification of the requirements of the Act, as well as training to all federal agencies on how to comply with the RFA.

The *Report on the Regulatory Flexibility Act, FY 2006* includes information about agency compliance with E.O. 13272. With the exception of the Department of State, all Cabinet-level departments have developed written plans in compliance with E.O. 13272. In general, agencies are complying with the requirements of the executive order. Advocacy continues to work with the agencies to bring them into full compliance with these important mandates of the E.O.

After developing the curriculum for a hands-on training program, Advocacy’s staff began classroom training for agencies in 2003. In May 2006, Advocacy made computer-based RFA training modules available to agencies so that agency employees can get initial or refresher RFA expertise on demand. By late 2007, Advocacy had trained the vast majority of federal agencies, departments, and independent commissions that write rules affecting small business.

Advocacy’s training is having a noticeable impact on the way agencies develop rules. Agencies that have been through training tend to notify Advocacy earlier in the process,

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<sup>2</sup> E.O. 13272 is on the Office of Advocacy’s website at <http://www.sba.gov/advo/laws/eo13272.pdf>.

submit draft documents, and seek Advocacy's assistance in finding small entity data. For example, when Congress enacted the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Act), it authorized the Food and Drug Administration (FDA) to promulgate rules in an expedited timeframe to protect the nation's food supply. In response to the Act, FDA published four final rules, each preceded by a notice of proposed rulemaking: prior notice of imported food shipments, registration of food facilities, establishment and maintenance of records, and administrative detention. The Act required FDA to publish the first three rules within 18 months or by December 12, 2003. FDA contacted Advocacy about the rules' impact on small businesses well before the proposed rules were published in the *Federal Register*. This allowed Advocacy to work closely with the FDA to reduce the economic effects of the rules on small businesses. As a result of the involvement of Advocacy and interested small businesses, FDA made several adjustments to the rules including the creation of the new automated commercial environment (ACE) database and a far less onerous notice requirement (twenty-four hours notice was reduced to two hours if the food is arriving by road, four hours if the food is arriving by rail, and eight hours if the food is arriving by sea); extending the registration update requirement from 30 days to 60 days; allowing those importers subject to the rule to check a food category titled "most or all" rather than requiring them to individually list food product categories that had been previously identified in the registration form; and exempting the food packaging industry, which consists primarily of small businesses, from the FDA registration and prior notice requirements. The FDA also gave small businesses more time to comply with the requirements.

#### **Impact of the RFA, SBREFA and E.O. 13272**

The SBREFA amendments to the RFA have been fairly successful. In general, agencies are paying closer attention to their RFA obligations. Some agencies submit their draft regulations to Advocacy early in the process to obtain feedback on their RFA compliance and small business impact. Early intervention by Advocacy and improved agency compliance with the RFA have led to less burdensome regulations. The Office of Advocacy estimates cost-savings totaling over \$50 billion since 2001.<sup>3</sup>

Although the RFA is doing a fairly good job in achieving cost savings for small entities, more needs to be done to protect small entities from excessive regulatory burden. In 2005, an Office of Advocacy study prepared by Mark Crain on *The Impact of Regulatory Costs on Small Firms*, determined that the overall cost of federal regulation totals \$1.1 trillion. The cost per employee for firms with fewer than 20 employees is \$7,647, 45 percent higher than their larger counterparts with 500 or more employees.<sup>4</sup> Legislative

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<sup>3</sup> A detailed listing of cost savings can be found in the Office of Advocacy's annual reports on the RFA which are located on Advocacy's website at <http://www.sba.gov/advo/laws/flex>.

<sup>4</sup> The Crain report is located at [http://www.sba.gov/advo/research/rs207tot\\_264.pdf](http://www.sba.gov/advo/research/rs207tot_264.pdf).

action is necessary to continue to lower regulatory costs and level the playing field for small entities.

#### **Suggestions for Modifying the Regulatory Process to Reduce Burdens on Small Entities**

The 110<sup>th</sup> Congress has the opportunity to amend the RFA and SBREFA to improve the regulatory climate for small entities. Even though the last few years have yielded a number of successes, there are certain weaknesses in the RFA that were not addressed through SBREFA. After eleven years of working with SBREFA, eight congressional hearings on the RFA and SBREFA, Advocacy's conference on the RFA<sup>5</sup>, and several Government Accounting Office (GAO) reports and testimonies<sup>6</sup>, now is a good opportunity to consider legislative improvements to the RFA. Advocacy believes that the following issues are the most crucial:

##### *Foreseeable Indirect Economic Impacts*

The biggest loophole in the RFA is that it does not require agencies to analyze indirect impacts. Agencies are required to consider the direct economic impact of a regulatory action on small entities, but that analysis deprives policymakers of a full understanding of a rule's likely impact on small entities.

The primary case on the consideration of direct versus indirect impacts for RFA purposes in promulgating regulations is Mid-Tex Electric Co-op Inc. v. Federal Energy Regulatory Commission, 249 U.S. App. D.C. 64, 773 F.2d 327 (1985) (hereinafter Mid-Tex). Mid-Tex addressed a Federal Energy Regulatory Commission (FERC) rule which stated that electric utility companies could include amounts equal to 50 percent of their investments in construction work in progress in their rates. In promulgating the rule, FERC certified that the rule would not have a significant economic impact on a substantial number of small entities. The basis of the certification was that virtually all of the regulated utilities fell outside of the meaning of the term "small entities" as defined by the RFA. Plaintiffs argued that FERC's certification was insufficient because it should have considered the impact on wholesale customers of the utilities as well as the regulated utilities. The court dismissed the plaintiffs' argument. The court concluded that the agency did not have to consider the economic impact of the rule on small entities that did not have to directly comply with the requirements of the rule.<sup>7</sup>

One of the most compelling examples of the importance of considering indirect impacts on small entities can be found in 2002 Immigration and Naturalization Service's (INS) rule on B-2 tourist visas. This rulemaking illustrates the importance of why the RFA

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<sup>5</sup> A copy of the conference proceedings for the RFA Symposium can be found at [http://www.sba.gov/advo/rfa\\_sym0905.pdf](http://www.sba.gov/advo/rfa_sym0905.pdf).

<sup>6</sup> For a listing of GAO reports and testimonies on the RFA, go to <http://www.gao.gov> and type Regulatory Flexibility Act in the search engine.

<sup>7</sup> Id. at 342.

should be amended to include having reasonably foreseeable indirect impacts analyzed in the rulemaking process. On April 12, 2002, INS published a proposed rule on *Limiting the Period of Admission for B Nonimmigrant Aliens*. The proposal eliminated the minimum six-month admission period of B-2 visitors for pleasure and placed the onus of explaining the amount of time for the length of stay on the foreign visitor. If the length of stay could not be determined, the INS agent would issue a visa for only thirty (30) days. Although it was foreseeable that small businesses in the travel industry could lose approximately \$2 billion as a result of the proposal, INS certified that the proposal would not have a significant economic impact on a substantial number of small entities. The basis for the certification was that the proposal applied only to nonimmigrant aliens visiting the United States as visitors for business or pleasure. Because the courts have interpreted the RFA as only requiring agencies to consider the economic impact of the proposal on the entities that the proposal will directly impact, the certification was not technically erroneous. Advocacy asserted that from the standpoint of good public policy, the agency had a duty to perform a regulatory flexibility analysis and to consider less burdensome alternatives for achieving their goal when the potential impact of a regulation was foreseeable and harmful to a particular industry.<sup>8</sup> Advocacy reiterated this position at a hearing before the House Committee on Small Business in June 2002.<sup>9</sup> Representatives from the travel industry also testified at that hearing about the potential economic impacts that their businesses would experience as a result of INS's actions. The rule was eventually withdrawn.

In addition, many times, especially with environmental regulation, the duty of regulating is passed on to the states without any corresponding analysis or requirements for states to consider less burdensome alternatives for small business. Amending the RFA to require federal agencies to consider indirect impacts will help state officials craft less burdensome regulatory alternatives. At least 92 percent of businesses in every state are small businesses.<sup>10</sup> The majority of states now have a small business regulatory flexibility process to ensure that state regulators consider their impact on small entities before adopting new regulations.<sup>11</sup> The rising number of states that have flexibility laws presents a compelling need for federal agencies to analyze the indirect impact of proposed rules so that states can benefit from the analysis when implementing federal mandates. Advocacy strongly supports amending the RFA to ensure that economic impact analyses include indirect economic impacts.

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<sup>8</sup> The Office of Advocacy's comment letter is located at [http://www.sba.gov/advo/laws/comments/ins02\\_0513.html](http://www.sba.gov/advo/laws/comments/ins02_0513.html).

<sup>9</sup> The Office of Advocacy's testimony before the U.S. House of Representatives, Committee on Small Business is located at [http://www.sba.gov/advo/laws/test02\\_0619.html](http://www.sba.gov/advo/laws/test02_0619.html).

<sup>10</sup> Office of Advocacy, U.S. Small Bus. Admin., REPORT ON THE REGULATORY FLEXIBILITY ACT, FISCAL YEAR 2005 47-48 (2006) available at <http://www.sba.gov/advo/laws/flex/05regflx.pdf>.

<sup>11</sup> Advocacy's model legislation and additional information about the state legislation initiative can be found at [http://www.sba.gov/advo/laws/law\\_modeleg.html](http://www.sba.gov/advo/laws/law_modeleg.html).

#### *Section 610 Review of Existing Regulations*

Small businesses often complain about the difficulties in dealing with the layers of regulations that agencies issue over time. Although a single proposed rule may not impose much of a regulatory burden, that rule, when added to numerous existing rules, may impose a crippling cumulative burden. Section 610 of the RFA requires agencies to periodically review their existing rules that may have a significant economic impact on a substantial number of small entities. The purpose of the review is to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes. Unfortunately, agency compliance with section 610 has historically been poor.

Small entities are limited in what they can do about burdensome regulations on the books. Although there are legal avenues that can be pursued to have burdensome rules reviewed, legal recourse is costly and time consuming. The automatic review of regulations afforded through section 610 not only results in the removal of burdensome regulations, it also saves small entities and federal agencies the hassle of having to resort to the legal system to obtain relief. However, limiting the review to only those regulations that the agency deemed to have a significant economic impact at the time of promulgation is problematic. Since new regulations are promulgated each year, the cumulative impact of regulations on small entities can be staggering, even if individually the regulations may not have a significant economic impact.

Moreover, a recent Government Accountability Office (GAO) report documents the need for more public participation and transparency in federal agencies' review of their existing regulations. The report, *Rexamining Regulations: Opportunities Exist to Improve Effectiveness and Transparency of Retrospective Reviews*, documents the successes and failures of federal agencies' efforts to review existing regulations.<sup>12</sup> The report spotlights agencies' implementation of section 610 of the RFA.

The Office of Advocacy recently unveiled its Regulatory Review and Reform Initiative (r3). r3 is designed to identify and address existing federal regulations that should be revised because they may be ineffective, duplicative, or out of date. r3 is a tool for small business stakeholders to suggest needed reforms and includes the agency review process under Section 610 of the Regulatory Flexibility Act. r3 will monitor the progress that agencies make toward achieving reforms and we believe federal agencies will do a better job of identifying and revising rules that need to be reformed because of the r3 initiative.

Advocacy recommends that the RFA be amended to review all rules periodically. This change would encourage agencies to revise their rules to ensure that regulations reflect current conditions and needs. Moreover, agencies should be required to submit an annual report on 610 review to Congress, the Office of Information and Regulatory Affairs, and the Chief Counsel for Advocacy. This report should include the status of pending reviews and the outcome of completed reviews.

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<sup>12</sup> See, [www.gao.gov/new.items/d07791.pdf](http://www.gao.gov/new.items/d07791.pdf).

*Codification of E.O. 13272*

E.O. 13272 has increased agency knowledge of and compliance with the RFA. One of the most important elements of E.O. 13272 is Section 3. Section 3 requires agencies to notify the Office of Advocacy of draft rules that will have a significant economic impact on a substantial number of small entities. It also requires agencies to give appropriate consideration to Advocacy's comments and address the comments in final rules. Small entities would benefit from an amendment to the RFA that would codify the requirements of E.O. 13272, ensuring that independent agencies are subject to the RFA requirements and creating long-term certainty for small entities.

Advocacy recognizes that section 604 of the RFA requires agencies to respond to comments, including those submitted by Advocacy, if an agency prepares a FRFA. However, it does not provide for Advocacy's comments to be addressed if the agency certifies the rule at the final stage of the rulemaking. This is particularly important since in FY 2006, 15.7 percent of Advocacy's comments were on improper certifications and 17.7 percent of Advocacy's comments were on inadequate or missing IRFAs. Under the current law, anywhere from 15.7 percent to 33.4 percent of Advocacy's comments could go unaddressed, if agencies decide to certify final rules in lieu of preparing a FRFA. Advocacy suggests that the RFA be amended to require agencies to provide written responses to all comments submitted by Advocacy, regardless of whether the agency prepares a FRFA or a certification for the final rule. Amending the RFA in this way sets into law a key component of E.O. 13272 and would provide further assurance that small entities have a legitimate voice in the rulemaking process.

**Conclusion**

The Office of Advocacy has reviewed the Committee Print distributed last week. The bill entitled "The Small Business Regulatory Improvement Act of 2008" addresses the issues outlined in my testimony. I commend this Committee for examining these important issues and I believe your legislation will go far to improve the RFA and help small entities. Thank you for allowing me to present these views. I would be happy to answer any questions.



# Statement of the U.S. Chamber of Commerce

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**ON:** SMALL BUSINESS REGULATORY IMPROVEMENT ACT OF 2008

**TO:** THE HOUSE COMMITTEE ON SMALL BUSINESS

**BY:** MARC FREEDMAN  
THE UNITED STATES CHAMBER OF COMMERCE

**DATE:** DECEMBER 6, 2007

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The Chamber's mission is to advance human progress through an economic, political and social system based on individual freedom, incentive, initiative, opportunity and responsibility.

The U.S. Chamber of Commerce is the world's largest business federation, representing more than three million businesses and organizations of every size, sector, and region.

More than 96 percent of the Chamber's members are small businesses with 100 or fewer employees, 70 percent of which have 10 or fewer employees. Yet, virtually all of the nation's largest companies are also active members. We are particularly cognizant of the problems of smaller businesses, as well as issues facing the business community at large.

Besides representing a cross-section of the American business community in terms of number of employees, the Chamber represents a wide management spectrum by type of business and location. Each major classification of American business—manufacturing, retailing, services, construction, wholesaling, and finance—is represented. Also, the Chamber has substantial membership in all 50 states.

The Chamber's international reach is substantial as well. It believes that global interdependence provides an opportunity, not a threat. In addition to the U.S. Chamber of Commerce's 96 American Chambers of Commerce abroad, an increasing number of members are engaged in the export and import of both goods and services and have ongoing investment activities. The Chamber favors strengthened international competitiveness and opposes artificial U.S. and foreign barriers to international business.

Positions on national issues are developed by a cross-section of Chamber members serving on committees, subcommittees, and task forces. More than 1,000 business people participate in this process.

TESTIMONY TO  
HOUSE SMALL BUSINESS COMMITTEE  
**Marc Freedman, Director of Labor Law Policy**  
**U.S. Chamber of Commerce**  
**Small Business Regulatory Improvement Act of 2008**  
**December 6, 2007**

Madam Chairwoman, Ranking Member Chabot, good morning. I am Marc Freedman, Director of Labor Law Policy for the U.S. Chamber of Commerce. Before I came to the Chamber in 2004, I was the Regulatory Counsel for the Senate Small Business Committee for more than five years under the chairmanships of Senators Bond and Snowe. During that time, my role was to oversee agency compliance with the Regulatory Flexibility Act and to suggest ways that it could be improved.

The Chamber unequivocally supports improvements to the Regulatory Flexibility Act (RFA) to close loopholes and clarify various terms that have led to agencies avoiding the requirements of the Act. We therefore are pleased to support your bill, the Small Business Regulatory Improvement Act of 2008 and commend you for pursuing this issue.

If we needed any reminder of what agencies will do to avoid assessing the impact of their regulations on small businesses, the recent regulation issued by the Department of Homeland Security holding employers accountable for the work authorization status of their employees based on the receipt of a Social Security Administration “no-match” letter should be more than sufficient. In that regulation, DHS did not address any of the complications and subtleties of trying to determine whether their regulation would have a “significant economic impact” on a “substantial number of small entities” in making their certification that the regulation did not trigger the full requirements of the RFA. They merely asserted that the regulation did not change

the underlying obligation of an employer to determine the work authorization status of its employees, and therefore this regulation represented no new burden.

The Chamber intervened in a case brought by an array of unions specifically to raise the Regulatory Flexibility Act compliance issue. Fortunately, Judge Charles Breyer of U.S. District Court for the Northern District of California saw through DHS's neglect of its rulemaking obligations and found that the agency had not supported its certification of no "significant economic impact on a substantial number of small entities" with an adequate factual basis as required by the Act. Currently, we are waiting to see how DHS addresses this shortcoming in an anticipated re-proposed regulation.

DHS's reasoning, if left unchallenged, would have set a dangerous precedent. Consider how that same logic—that the underlying obligation on the employer was not changed by a regulation—could be applied by other agencies such as OSHA. The Occupational Safety and Health Act mandates that employers provide a workplace "free from recognized hazards that are causing or are likely to cause death or serious physical harm"—all of OSHA's regulations are merely detailed examples of these hazards and how employers must protect their employees from them. If OSHA was to adopt DHS's logic—that any regulation did not change the underlying obligation of the employer—the agency would never have to determine the impact of a proposed regulation on small businesses and therefore would never conduct a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel review taking input from actual small businesses; and never have to produce a small entity compliance guide—requirements for which were recently enhanced in the minimum wage package passed earlier in this session.

Against this backdrop, the Chamber believes making the RFA as effective as possible is imperative. While we are often associated with our large members, the truth is that 96 percent of U.S. Chamber members are actually small businesses with 100 employees or less. Everyone acknowledges that regulations impact small businesses more harshly than large businesses. If we are serious about keeping our small businesses competitive with global competition, we must make sure this act has the impact Congress intended when it passed the Regulatory Flexibility

Act more than 25 years ago, and amended it with the Small Business Regulatory Enforcement Fairness Act in 1996.

Your bill would make several important improvements to the Regulatory Flexibility Act. Perhaps the most significant is requiring agencies to consider the indirect impact of regulations when calculating the impact of regulations on small businesses. This is particularly helpful with respect to Environmental Protection Agency (EPA) regulations where the agency has claimed that, because some of their regulations are enforced by the states, these regulations only have an indirect impact and therefore do not trigger the range of requirements under the RFA and SBREFA. One example is with the National Ambient Air Quality Standards (NAAQS) under the Clean Air Act which delegates to the states the authority to develop the implementation plans on how comply with the NAAQS. Although ambient air quality standards can impose significant economic costs on businesses that may have to reduce their activities in order to comply with the state implementation plan and meet the ambient air quality standards, EPA does not comply with the RFA when it develops the standards or during the approval of the state implementation plans. The EPA argues that the RFA does not apply because the ambient air quality standards and state implementation plans only regulate states which are not small entities under the RFA.

Another important problem your bill addresses is improving agency compliance with Section 610—the provision that requires agencies to review their regulations after 10 years to determine if they should remain as is, or be modified to better fit the realities of the small businesses who must comply with them. Your bill makes clear that the agency is to determine whether the regulation has a significant economic impact on a substantial number of small entities at the time of the review. The Government Accountability Office concluded that the original text of the legislation was not clear whether this impact applied to the time the regulation was issued, or when it was being reviewed. This confusion allowed agencies to legitimately claim that they were unsure how to proceed.<sup>1</sup>

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<sup>1</sup> GAO Report, "Regulatory Flexibility Act: Agencies' Interpretations of Review Requirements Vary," GGD-99-55, April 2, 1999.

Indeed, the Government Accountability Office has done quite a few studies on the Regulatory Flexibility Act showing how agencies have failed to comply with it and repeatedly citing lack of clarity in the law's terms as a key reason. I think this statement from a 2006 testimony makes the point very well about what is needed to make the RFA as effective as we all want it to be:

GAO's past work suggests that Congress might wish to review the procedures, definitions, exemptions, and other provisions of RFA to determine whether changes are needed to better achieve the purposes Congress intended. In particular, *GAO's reports indicate that the full promise of RFA may never be realized until Congress revisits and clarifies elements of the Act, especially its key terms, or provides an agency or office with the clear authority and responsibility to do so.* Attention should also be paid to the domino effect that an agency's initial determination of whether RFA is applicable to a rulemaking has on other statutory requirements, such as preparing compliance guides for small entities and periodically reviewing existing regulations.<sup>2</sup>

Madam Chair, I agree with the GAO that if we are serious about improving the Regulatory Flexibility Act the most important thing would be for Congress to make clear what it means by the terms "significant economic impact" and "substantial number of small entities." These two phrases drive the overall question of whether an agency must apply the RFA to any given regulation. Agencies have taken maximum advantage of the "flexibility" in the Regulatory Flexibility Act to define these terms differently as they choose for any given regulation with the goal being to credibly define these terms so that the regulation is regarded as not having this level of impact, and thus avoid having to complete the requirements of the RFA.<sup>3</sup>

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<sup>2</sup> Testimony of J. Christopher Mihm, Managing Director Strategic Issues Before the Subcommittee on Commercial and Administrative Law, Committee on the Judiciary, House of Representatives, July 20, 2006, "Congress Should Revisit and Clarify Elements of the Act to Improve Its Effectiveness," (GAO-06-998T).

<sup>3</sup> See, Testimony of Victor Rezendes, Managing Director Strategic Issues Team, Before the Committee on Small Business, U.S. Senate, April 24, 2001, "Regulatory Flexibility Act: Key Terms Still Need to Be Clarified," (GAO-01-669T); "In particular, Congress may need to clearly delineate—or have some other organization delineate—what is meant by the terms "significant economic impact" and "substantial number of small entities." The RFA does not define what Congress meant by these terms and does not give any entity the authority or responsibility to define them governmentwide. As a result, agencies have had to construct their own definitions, and those definitions vary. Over the past decade, we have recommended several times that Congress provide greater clarity with regard to these terms, but to date Congress has not acted on our recommendations." And Rezendes Testimony before the Committee on Small Business, U.S. House of Representatives, March 6, 2002, "Regulatory Flexibility Act: Clarification of Key Terms Still Needed," (GAO-02-491T). See also, GAO Report to

To bring clarity to these terms, there are various approaches Congress could take. While these two terms cannot be defined the same for all regulations, or even for all regulations from a specific agency, it is possible to establish the parameters and the elements that must be considered. Doing so would not only keep agencies honest about how they apply the RFA, it would also set benchmarks so that those of us who monitor agencies' compliance with the RFA would have some way to tell if they had done what they are supposed to do.

One way to accomplish the goal of clarifying these terms would be to authorize the Chief Counsel of Advocacy to promulgate a rulemaking defining these terms, and other requirements of agency compliance with the RFA. Giving the Chief Counsel authority to issue regulations has been proposed before, most recently in the last Congress by Congressman Manzullo in H.R. 682, the Regulatory Flexibility Improvements Act, and also by Senator Bond back in the 107<sup>th</sup> Congress in his bill, S. 849, the Agency Accountability Act. In the alternative, Congress could specify what it meant by these key terms and instruct agencies that they are to incorporate these elements as they apply these terms to their regulations.

For those regulations when an agency's certification is still not adequately supported, another change I think would be most helpful would be to permit the judicial review of an agency's certification decision at a time closer to when that decision is made, rather than having to wait until the final regulation is issued as under the current system. This would preserve the ability of small businesses to get their input into the rulemaking at a time when it can still have an impact.

An excellent example of where this would have been particularly helpful is the recent case brought by the Aeronautical Repair Station Association (ARSA), against the Federal Aviation Administration (FAA)<sup>4</sup> regarding its regulation requiring contractors and subcontractors at any tier to establish mandatory drug and alcohol testing programs for

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the Chairman of the Committee on Small Business, U.S. Senate, "Regulatory Flexibility Act: Agencies' Interpretations of Review Requirements Vary," April, 1999, (GAO/GGD-99-55).

<sup>4</sup> *Aeronautical Repair Station Association, Inc. v. FAA*, No. 06-1091, 2007 U.S. App. LEXIS 16920 (D.C. Cir. July 17, 2007).

employees performing maintenance functions for the aviation industry. On July 11, the U.S. Court of Appeals for the District of Columbia Circuit found that the FAA had not fulfilled its obligations under the RFA. In certifying that the regulation would not trigger the RFA, and therefore not require an Initial Regulatory Flexibility Analysis (IRFA), FAA had not included various small businesses in its assessment of the impact of the regulation because it described the various levels of contractors that would have to comply with this regulation as “indirectly” affected and therefore not covered. An industry survey, however, showed that between 12,000 and 22,000 subcontractors would be affected, compared to the 297 subcontractors cited by the FAA.

As part of the IRFA that was not conducted, the FAA did not evaluate less burdensome alternatives that were offered by ARSA and would likely have been considered had the FAA fulfilled their obligations under the RFA. Although the Court found in favor of ARSA, it still upheld the substance of the final rule letting it go into effect, but remanding it for the limited purpose of requiring FAA to comply with RFA. Had the right of judicial review been allowed earlier in the process, the certification would have been successfully challenged, and the input from ARSA about less burdensome, but still effective, alternatives would have been provided when it could have made a difference in fashioning the regulation. Under the current court ruling, the agency is obligated only to go back and comply with the Reg Flex Act requirements—it has no obligation to modify the final rule and will likely find it difficult to retroactively modify a final rule that is currently in effect, even if more small business friendly alternatives have merit.

Waiting until a final regulation has been issued means that the certification decision might have been made years before, and the agency will have expended considerable effort and resources on finalizing the regulation, thereby creating an argument for keeping it as is, even if it has badly mischaracterized its impact. By that time the regulation is written, and in some cases—such as the ARSA challenge—may still go into effect, as the question of whether to stay the regulation is up to the judge. Allowing this review to occur on an expedited basis, when the certification decision is made public, presumably as part of the Notice of Proposed Rulemaking,

would preserve the impact of the small business input and then allow the rulemaking to go forward as it should have.

The ARSA case also demonstrates the importance of the provision in the bill specifying that “foreseeable indirect impacts” being included in an agency’s threshold analysis to determine the impact of a regulation. Had this provision been in place, the agency would not have been able to dismiss the impacts on contractors and subcontractors as “indirect” and would most likely have recognized that the Regulatory Flexibility Act applied to this regulation.

Madam Chair, the Chamber recognizes your long history of support for the Regulatory Flexibility Act and applauds your leadership in introducing the Small Business Regulatory Improvement Act of 2008. We look forward to working with you to move this important bill.



## Testimony

**of Dyke F. Messinger**  
*Power Curbers, Incorporated*

*on behalf of* the National Association of Manufacturers

*before the* Committee on Small Business

United States House of Representatives

*Hearing on* "Legislation to Improve the Regulatory Flexibility Act"

**December 6, 2007**

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**COMMENTS OF THE NATIONAL ASSOCIATION OF MANUFACTURERS  
BEFORE THE**

**COMMITTEE ON SMALL BUSINESS  
U.S. HOUSE OF REPRESENTATIVES**

**DECEMBER 6, 2007**

Chairwoman Velázquez, Ranking Member Chabot and members of the Committee on Small Business, thank you for the opportunity to testify today on behalf of the National Association of Manufacturers (NAM) about the Regulatory Flexibility Act and the work of this committee to improve it.

The NAM is the nation's largest industrial trade association, representing small and large manufacturers in every industrial sector and in all 50 states. Three-quarters of the NAM's membership are small and medium manufacturers. Headquartered in Washington, D.C., the NAM has 10 additional offices across the country. We represent the 14 million men and women who make things in America.

My name is Dyke Messinger and I am the President and CEO of Power Curbers, Inc. We make mechanized construction equipment that turns concrete into curbs and gutters. We employ 104 people in Salisbury, NC; Cedar Falls, IA; and Whitehouse, TN. We sell our equipment in over 80 countries.

The NAM's mission is to enhance the competitiveness of manufacturers by shaping a legislative and regulatory environment conducive to U.S. economic growth, and to increase understanding among policymakers, the media and the general public about the vital role of manufacturing to America's economic future and living standards.

The manufacturing community — especially smaller manufacturers — welcomes today's hearing. As the final 2004 OMB Report to Congress on the Costs and Benefits of Federal Regulations notes, federal regulations hit the manufacturing sector especially hard. Because manufacturing is such a dynamic process, involving the transformation of raw materials into finished products, it creates more environmental and safety issues than other businesses. Thus, environmental and workplace health-and-safety regulations have a disparate impact on manufacturers.

Another report entitled The Impact of Regulatory Costs on Small Firms, by Mark Crain and Thomas Hopkins, issued in 2001 and updated by Dr. Crain in 2005 for the Office of Advocacy of the Small Business Administration, makes the same point. The burden of regulation falls disproportionately on the manufacturing sector.

In this most recent report, Dr. Crain found that the manufacturing sector shouldered \$162 billion of the \$648 billion onus of environmental, economic, workplace and tax-compliance regulation in the year 2004.

Overall, Crain found that the per employee regulatory costs of businesses with fewer than 20 employees were \$7,647, or 40 percent more than the cost per worker of \$5,282 for firms with more than 500 employees.

In manufacturing, this disparity was even wider. The cost per employee for small firms (meaning fewer than 20 employees) was \$21,919 or 118 percent higher than the \$10,042 cost per employee for medium-sized firms (defined as 20–499 employees). And it was 150 percent higher than the \$8,748 cost per employee for large firms (defined as 500 or more employees).

In December 2003, the NAM released a report, "How Structural Costs Imposed on U.S. Manufacturers Harm Workers and Threaten Competitiveness," which has received considerable attention from media, business and policy experts.

This report, which is available at [www.nam.org/costs](http://www.nam.org/costs), examined structural costs borne by manufacturers in the United States compared to our nine largest trading partners: Canada, Mexico, Japan, China, Germany, the United Kingdom, South Korea, Taiwan and France. The principal finding was that structural costs—those imposed domestically “by omission or commission of federal, state and local governments”—were 22.4 percent higher in the U.S. than for any foreign competitor. We subsequently updated that study and found them to be 31.7% higher in 2006.

The structural costs included regulatory compliance, along with excessive corporate taxation, the escalating costs of health and pension benefits, the escalating costs of litigation and rising energy costs.

In order to determine the effect of regulation on domestic manufacturing compared to our main competitors, the NAM Report used pollution-abatement expenditures because they are the only cross-country regulatory compliance cost data available. Thus, the 31.7 percent higher structural costs that U.S. manufacturers face in comparison with our largest trading partners are significantly understated because the regulatory component includes only pollution-abatement expenditures. Even so, just including these specific costs puts the United States at a trade-weighted disadvantage of at least 3.5 percentage points. Only South Korea's pollution-abatement costs are higher; all other U.S. trading partners, including European nations, have much lower regulatory costs.

As a result, we welcome the leadership of Chairwoman Velázquez in this Congress on making improvements to the Regulatory Flexibility Act (RFA). This committee has long recognized the disproportionate burden of regulatory costs on small businesses and especially small manufacturers. We are anxious to assist you in this effort.

It is our understanding that you intend to introduce legislation to improve federal agency compliance with the regulatory flexibility act and that it would contain provisions to improve periodic review of regulations impacting small business (Section 610), account for indirect effects of those regulations, and that you will codify the Office of Advocacy's relationship with federal agencies. These are all sound improvements and the NAM and its members are supportive of your efforts.

First, let me say that the importance of including indirect economic effects in regulation flexibility analyses is paramount. A timely example of agencies not being able to consider the impact they are truly having on small businesses is the EPA's National Ambient Air Quality Standards for Ozone. Because the implementation of NAAQS standards is done through the regulation and approval of state implementation plans, there are said to be no direct effects on small entities because states are not small entities. This is clearly contrary to what Congress intended when it passed the RFA. And a rule, as significant as this one will be to local communities and their small business economies, should be reviewed for its impact. This legislation obviously won't change how this rule is made. But future rules should be judged on both their direct and indirect impacts.

Periodic review often referred to as a Section 610 analysis has always been an underperforming provision. There was great hope that it would rationally reduce or eliminate some burdens on small business that had outlived their usefulness or had not appropriately considered the concerns of small business when they were first promulgated. A Government Accountability Office report from July of this year suggested that of the agency retrospective reviews that were mandatory, few changes to the underlying rules occurred. Although their recommendations were not specific to changes to Section 610 reviews, it speaks to the need for change. We are hopeful that your enhanced reporting requirements will create the necessary environment for better retrospective review.

There are also circumstances where an individual rule is not particularly burdensome or a challenge to many small businesses. But the cumulative effect of that rule and many others affecting a particular sector or type of business can be crushing. The total burden of regulation including tax paperwork can cost businesses the use of an employee dedicated solely to compliance, thousands of dollars in outside accountants or environmental consultants, or a loss of focus from critical business needs. They are not always easy to quantify, but the current loophole of providing this analysis “to the extent practicable” gives agencies too large of an opportunity to walk away from this responsibility. Just as “where feasible” as a limitation to the review of the number of small entities affected seriously weakens the requirement. Changes to this limiting language in several parts of the RFA will go a long way to improving agency compliance and analysis.

The NAM was also very supportive of former Chairman Manzullo's H.R. 682, the Regulatory Flexibility Improvements Act introduced in the 109<sup>th</sup> Congress. We believe there are a few provisions of that bill that would strengthen your legislation. It is worth reviewing the case for giving the Chief Counsel for Advocacy at SBA regulatory authority. Court cases involving the Chief Counsel's interpretations have failed to provide the proper weight to the interpretations of the RFA by that office. Rulemaking authority would provide that certainty. And since over 80% of the government's billions of hours of paperwork burden imposed on the American people come from the IRS, efforts to fix the loopholes by which the IRS avoids compliance with the RFA would be welcome.

Again, Madam Chairwoman, thank you for this opportunity to testify. I would be happy to respond to any questions.

Testimony before the United States Congress on behalf of the



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Testimony of

**Andrew M. Langer**  
Senior Manager, Regulatory Affairs

Before the

**The House Committee On Small Business**  
**Hearing on Small Business Regulatory Burdens**

**The Context of Regulation:**  
**Reducing the Incremental Costs**

on the date of

**December 6, 2007**

Chairwoman Velazquez and Members of the House Committee on Small Business:

On behalf of the hundreds of thousands of small-business owners represented by the National Federation of Independent Business, thank you for the opportunity to discuss with you the burden of regulatory paperwork imposed by the federal government and to offer NFIB's insights about how to improve the way in which the federal government goes about reducing the amount of paperwork filled out by America's small businesses each year.

I attended your hearing on regulatory burdens several weeks ago, and I appreciate your invitation to come before you to discuss these burdens in more detail. My testimony is going to cover two main areas: a presentation of the general regulatory and paperwork burden at both the macro and microeconomic levels, and then offer recommendations of changes to federal law and policy which will work to reduce these burdens.

#### Introduction

I believe that at the outset, it is important to lay out just who we are talking about here, and who NFIB represents. When NFIB talks about small business, we are generally not talking about businesses which fit into the larger end of the Small Business Administration's definitions for small business. Ninety percent of NFIB members have fewer than 20 employees. Moreover, the typical NFIB member employs ten people and reports gross sales of between \$350,000 and \$500,000 per year. NFIB's national membership spans the spectrum of business operations, ranging from one-person cottage enterprises to firms with hundreds of employees. However, all NFIB members have one thing in common; their businesses are independently owned.

Clearly, we are talking about the truly small businesses—businesses whose priorities and abilities to handle regulatory challenges are greatly different from their larger counterparts. Being a small-business owner means, more times than not, you are responsible for everything (ordering inventory, hiring employees, and dealing with the mandates imposed upon your business by the federal, state and local governments). That is why government regulations, and the paperwork they generate, should be as simple as possible. The less time our members spend

with “government overhead,” the more they can spend growing their business, employing more people and growing America’s economy.

Unreasonable government regulation, especially onerous paperwork burdens, continues to be a top concern for small businesses<sup>1</sup>. Regulatory costs per employee are highest for small firms, and our members consistently rank those costs as one of the most important issues that NFIB ought to work to change. On several occasions, I have testified before Congress on the most recent report commissioned by the Small Business Administration’s Office of Advocacy, estimating the regulatory compliance costs for firms with fewer than 20 employees.

Five years ago, that cost averaged \$6,975 per employee, per year, but now that figure has been updated with a peer review process that lends even greater credence to the research. Unfortunately for small-business owners, however, the new data isn’t good — the cost of regulation for small businesses has risen by nearly 10 percent, to \$7,647 per employee, per year.<sup>2</sup> This is due in no small measure to the continued growth of the regulatory state: according to the Competitive Enterprise Institute’s Wayne Crews, the last two years have brought an average of approximately 4,000 new rules each year<sup>3</sup>.

This means that for one of NFIB’s average members, with ten employees, those costs now approach a total of \$80,000 annually. For a business operating on a shoestring, such costs can be devastating.

But those numbers drop when you get above 20 employees—on average by as much as a full third. Why such a stark contrast? NFIB’s Research Foundation has done numerous surveys on paperwork and regulatory compliance, and it has found that businesses with between 20 and 35 employees hire a regulatory professional. Usually, this is someone with expertise in labor regulations and human resources, as these are the rules with the most general application.

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<sup>1</sup> In NFIB’s publication, *Problems and Priorities*, paperwork ranked 8<sup>th</sup> out of 75 major problems faced by small business.

<sup>2</sup> Crain, W. Mark, *The Impact of Regulatory Costs on Small Firms, 2005*, <http://www.sba.gov/advocacy/research/rs264.pdf>

<sup>3</sup> 4,101 final rules in 2004, 3,943 final rules in 2005. Crews, Clyde Wayne, *Ten Thousand Commandments, 2006 edition*.

Also, as the business grows, measures taken to comply with federal regulations can have their cost spread around a larger pool of employees. These “economies of scale” reduce those per-employee costs as well.

However, until those businesses reach that magic number, it is generally the small business owner, that owner’s spouse, or some trusted employee within the business who is responsible for ferreting out regulatory obligations and figuring out what needs to be done in order to be in compliance. Because these individuals do not have the prior regulatory experience or training, it takes far longer for them to become aware of their obligations under the law, and just what those obligations entail.

#### **The Macroeconomic Costs, and the “Context” of Regulation**

The average NFIB member cost of nearly \$40,000 per year for regulations, the approximately \$7,700 per employee per year cost, those are the microeconomic figures—what each individual small business faces. But the problem is truly staggering when one looks at the general regulatory state.

While the Office of Information and Regulatory Affairs reports a cost of \$44 billion<sup>4</sup> for all major rules, this presents only a part of the regulatory snapshot. OIRA only reviews **major** rules, the dozen or so rules from a previous 10-year period whose annual cost is in excess of \$100 million. But it’s not the “major” rules that are most damaging. I have testified before on regulation being “death by a thousand pinpricks” for small business. It’s not one single rule that is the culprit, but the thousands of smaller rules with incremental impacts that present a slow-bleed for America’s small business. Those rules add up to an annual regulatory cost of \$1.14 **trillion** annually, according to Wayne Crews at CEI—an amount essentially equivalent to the entire federal budget!

Paperwork itself is a tremendous culprit. In the Office of Management and Budget’s 2005 report on paperwork, the Information Collection Budget (ICB),<sup>5</sup> they denote an increase of the

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<sup>4</sup> [http://www.whitehouse.gov/omb/inforeg/2006\\_cb/2006\\_cb\\_final\\_report.pdf](http://www.whitehouse.gov/omb/inforeg/2006_cb/2006_cb_final_report.pdf)

<sup>5</sup> <http://www.whitehouse.gov/omb/inforeg/infocoll.html>

paperwork burden faced by all Americans of 441 **million** hours. Sadly enough, represents an increase overall of only 5.5 percent!<sup>6</sup>

In terms of the paperwork burden imposed by regulations themselves, NFIB's own Research Foundation has conducted in-depth studies of the problem being faced by small businesses. They concluded overall that the cost of paperwork averages roughly \$50 per hour. In addition, the following conclusions were reached<sup>7</sup>:

1. The individual(s) completing and maintaining paperwork and records in a small business is dependent on the subject matter of the paperwork and the size of the firm. Owners most frequently handle paperwork and record-keeping related to licenses and permits (55 percent of firms), purchases (46 percent), and clients/customers (46 percent). They least frequently deal with financial (27 percent) and tax (12 percent) records. Three of four pay to have someone (another firm) outside handle their tax paperwork. Paid employees customarily do most of the paperwork and record-keeping in about 25 – 30 percent of firms. Employees are much more likely to do so in larger, small businesses than in the smallest ones regardless of subject matter (except tax). Unpaid family members do the paperwork in less than 10 percent of cases.
2. The cost of paperwork also varies by subject matter and firm size. The more paperwork and record-keeping that must be sent outside, the more expensive the paperwork and record-keeping. Owners of larger small firms pay higher average prices per hour because they are more likely to send their paperwork to outside professionals and because the value of their time on average is higher.
3. The estimated average per hour cost of paperwork and record-keeping for small businesses is \$48.72. By subject matter the average per hour cost is: \$74.24 for tax-related, \$62.16 for financial, \$47.96 for licenses and permits, \$43.50 for government information requests, \$42.95 for customers/clients, \$40.75 for personnel, \$39.27 for purchases, and \$36.20 for maintenance (buildings, machines, or vehicles).
4. The typical small business employs a blend of electronic and paper record-keeping. Less than 10 percent use paper exclusively and a handful use only electronic means. The type of record most frequently completed and maintained on paper is licenses and permits.
5. No single difficulty creates the government paperwork problem. The most frequently cited problem is unclear and/or confusing instructions (29 percent). The second most frequently cited difficulty is the volume of paperwork (24 percent). Duplicate information

<sup>6</sup> ICB at i.

<sup>7</sup> NFIB Research Foundation National Small Business Poll, Vol. 3, Issue 5, *Paperwork and Recordkeeping*, 12-03, [http://www.nfib.com/PDFs/sbpoll/sbpoll12\\_2003.pdf](http://www.nfib.com/PDFs/sbpoll/sbpoll12_2003.pdf)

requests (11 percent) place third, followed by maintenance of records that ordinarily would not be kept (10 percent) and requests for inaccessible or non-existent information (9 percent). Twenty (20) percent could not decide.

While the use of computers by small businesses and small-business owners has certainly helped reduce the burden of regulations, technology alone cannot solve the problem. More than filing forms and storing copies, paperwork requirements involve understanding what the government wants and how they want it, gathering the necessary information and organizing it properly, determining what to keep and for how long, etc. Then there is the cost. Even with the most efficient computer equipment, documentation is not cheap. People must organize and input the necessary data, and people are expensive.

According to research by the NFIB Research Foundation, 92 percent of small businesses use computers in some aspect of their business. Eighty-two percent of small businesses have internet access, and of those, 57 percent have high-speed internet access. Half of the businesses that use the internet use it to find out regulatory information, and the smaller of small businesses are more likely to use the internet to educate themselves. They use it for specific searches, and to sift through information.<sup>8</sup>

But taken in the context of the ICB, the costs continue to be startling. If you only look at the average costs our polling found, then at the most macro of economic levels, the cost of the *increase* in paperwork alone amounts to nearly \$21.5 *billion* annually!<sup>9</sup> The total cost of paperwork therefore is nearly half a *trillion* dollars (roughly \$409 billion).<sup>10</sup>

Some people might argue that the increase in paperwork from the ICB is only 5.5 percent overall. But that only serves to mask the real issue: 441 million hours is an enormous amount of time—time that drags on everyday Americans, and \$21.5 billion is real money for real small businesses.

<sup>8</sup> NFIB National Small Business Poll Volume 4, Issue 8, "Telecommunications," <http://www.nfib.com/object/telecomm.html>

<sup>9</sup> \$48.72 X 441 million hours equals \$21,485,520,000

<sup>10</sup> \$48.72 X 8.2 billion hours equals \$409,248,000,000

While some might quibble that this is only a marginal increase—one cannot deny that the baseline number is a huge one. A system that measures its paperwork burdens in the billions of hours and in which citizens' spending on paperwork is roughly equivalent to 85 percent of what the nation spends on defense each and every year is a system doomed to collapse<sup>11</sup>. It requires careful examination—a recognition that a serious problem exists and then taking the appropriate steps to see that problem solved. But there is no “magic bullet” here. While tax paperwork is responsible for a substantial portion of the paperwork burden, there is no single regulation responsible for the lion’s share of that burden.

As I said earlier, it’s the thousands of regulations, with their incremental costs, that create this “weight”. Because regulations are created and expanded without regard to their context, this is simply going to continue. What is meant by context? Regulations are, essentially, created in a vacuum—generally without regard to overall regulatory burdens created by the agency, certainly without regard to pre-existing regulatory costs. Each regulation is measured and judged based on its own individual costs.

The problem is that taken individually, each incremental cost can appear inconsequential. A new regulation by an agency might add 7.5 hours of training time per employee per quarter of a year, and taken alone, that might seem to be a harmless mandate. But let’s assume for a moment that this agency already has regulatory requirements that cumulatively require 150 hours of time. Assuming a 7.5 hour work day, that’s already 20 days of time that one agency’s regulatory burden consumes. Another 30 hours of training per year amounts to another 4 days of time—a twenty percent increase.

Further, if we assume that a full-time equivalent’s “work year” is roughly 250 days, we’re talking nearly ten percent of an employee’s time is being taken up for the mandates of one agency. But no small business is regulated by only one federal agency, of course. There could be EPA, OSHA, Transportation, Labor, and a variety of other federal regulators. If four of these

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<sup>11</sup> In FY2005, DOD actually spent just over \$475 billion – about \$66 billion more than it cost Americans to fill out their paperwork for the federal government.

agencies each pose time burden of 24 days, that's 96 days that have now been lost to federal regulatory mandates—leaving 154 days for the business of the small business.

Time is one of a small business' most-precious and most-finite resources. Every day, every hour is important. But because, by comparison, federal agencies have nothing but time, they have no compunction against taking an hour here, and an hour there. And like the Washington proverb, "a billion here, a billion there, pretty soon you're talking about real money," the hours that the federal government robs from these businesses does add up.

We therefore believe, and will discuss in our recommendations, that some measure of accounting for this needs to be done.

#### **Recommendations for Regulatory Reform in Congress**

We are gratified that Congress is once again picking up the mantle of regulatory reform to help small business. In dealing with regulatory burdens, there are two ways of looking at the problem: you can reduce the number and scope of proposed and existing regulations themselves (the supply side); and at the same time you have to look at how to change the time needed to figure out how to comply with them (the demand side).

On that former side, we have a series of recommendations for legislation dealing with proposed regulations, the burdens they impose, as well as for reviewing agency practices with regards to new regulations and regulations already on the books. We believe that the following are the basic principles that ought to be contained in any legislation proposed:

1. **Modify Section 610 of the Regulatory Flexibility Act:** Section 610 of the Regulatory Flexibility Act (RFA) mandates that federal agencies develop a plan for the periodic review of regulations that have or will have a significant economic impact on a substantial number of small entities. Unfortunately, agencies either fail to engage in the proper reporting, or when they do, their reports do not have any useful information. This is partially a problem of oversight, and partly a problem of guidance, and while the Office of Advocacy has done an excellent job in training agencies in RFA compliance, without stringent reporting guidelines, there is a limit to what Advocacy can accomplish.

Modifications to Section 610 ought to specifically outline what should be included in such reports. Section 610 ought to be expanded to cover the review of all rules (currently, such review only cover regulations the agency considered "economically

significant" at the time they were proposed. Section 610 reviews ought to be judicially reviewable as well.<sup>12</sup> Also, OIRA should be required to report on reviews that were undertaken in the previous year, when they annually report to Congress on the costs and benefits of regulation.

- 2. Include Indirect Economic Impacts in Regulatory Review:** One of the ongoing deficiencies in both the RFA and the Small Business Regulatory Enforcement Fairness Act (SBREFA) has been that *indirect* economic effects on small businesses go ignored in these evaluations. Either ancillary impacts aren't taken into account, or industries not directly affected but nevertheless impacted by the rulemaking are ignored. In the most recent hearing on regulatory burdens held by the Small Business Committee on November 15, 2007, Joe Rajkovich from the Owner-Operator Independent Driver Association testified on this very issue. He suggested that Congress ought to require, "agencies to consider the impact of its actions on small businesses who are not those in the regulated community" but who are impacted by the agency action.<sup>13</sup>
- 3. Codification of Executive Order 13272:** Among other things, Executive Order 13272 strengthened small business protections under the RFA and SBREFA by setting out a formal working relationship between OIRA and SBA's Office of Advocacy, creating additional responsibilities for federal agencies in complying with laws protecting small entities, and laying out reporting requirements for compliance with the Executive Order. Because such orders are at the mercy of whichever chief executive is sitting in the White House these programs, as well as those portions of Executive Order 12866 that haven't been codified as well, should be made into law.
- 4. Strengthen SBREFA's Compliance Guide Mandates:** Small businesses continue to be frustrated with the instructions they are supposed to follow in figuring out how to comply with new regulations. Section 212 of SBREFA was supposed to help alleviate this problem by requiring agencies to publish small business compliance guides with each new final rule. Agencies should be required that whenever a rule requires a final regulatory flexibility analysis, then they must also publish a compliance guide (in plain language) specifically geared towards small businesses, and that such a guide should be done on the date the rule becomes effective<sup>13</sup>. They should also be required to annually report to the Office of Advocacy on their compliance with this rule.
- 5. Expand Small Business Protections to the IRS:** As discussed above, the IRS accounts for the largest share of the regulatory and paperwork burdens faced by small businesses, and while NFIB suggests that the "bright line" between the OMB and the IRS be removed by the administration, Congress can also play a distinct role. The RFA's jurisdiction over the IRS must be clarified. IRS rules ought to be subject to SBREFA panels, similar to those faced by proposed OSHA and EPA regulations, and most importantly, small business protections must expressly cover all new information

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<sup>12</sup> Testimony of Joe Rajkovich before the House Small Business Committee, November 15, 2007 at 3.

<sup>13</sup> Currently, general compliance guides are mandated to be published at the same time the rule goes into effect.

collection requests (ie, questions) and not just new forms, as the IRS currently interprets the law.

6. **Require that Agencies Publish the Name and Direct-Dial Phone Number For A Regulation's Principal Author:** One of the most problematic situations for a small business owner is knowing who to turn to when a question arises. Though single agency points of contact for regulatory questions has been helpful, there are certain questions which require an in-depth expertise which these contacts might not otherwise have. We believe that the person primarily responsible for a regulation's shepherding through promulgation would have the greatest expertise on a regulation---and if a small business owner is going to be required to follow a regulation, then it's only courteous and fair that the person who wrote the regulation be made regularly available for questions about that regulation arise.
7. **Financially Penalize Agencies Who Ignore Their Regulatory Flexibility Obligations:** As was testified to on November 15, many small business owners and their representatives believe that agencies only pay scant attention to their obligations under the law. Part of the reason for this is that there is no penalty when the agencies treat their obligations in a pro-forma manner. We recommend that should it be found that they affirmatively ignored their obligation, that some financial penalty accrue to the agency, possibly by cutting that agency's travel budget.
8. **Expand the Purview of the Regulatory Fairness Boards to Include Review of Agency Compliance with Regulatory Flexibility Laws:** Currently, there exists no body which engages in an across-the-board, comprehensive review of agency compliance. Some have discussed putting this review in the hands of Congress, some have discussed creating an independent commission to engage in such a review. We believe that the Regulatory Fairness Program administered by the National Ombudsman for Small Business at the SBA has been a rousing success. Our members use this program and have gotten great results from the personnel at the SBA. We believe that these successes ought to be built upon---and that expanding this program's scope to include RegFlex compliance review would be appropriate.
9. **Mandate That Each Agency Annually Publish An Accounting of Their Total Regulatory Cost:** As mentioned earlier, currently the only annual accounting of regulatory costs done by the federal government is performed by OIRA, and it only looks at the costs of major regulations for the previous 10 years. If we want to get an honest, accurate look at regulatory burdens, then each agency ought to be accounting for its fair share. This would actually simplify matters for both OIRA and members of the public who are interested in assessing these costs: OIRA could still publish its report on the costs of major rules, but they could also take the numbers put forth by each agency as to the costs of *all* of their rules (major and not-so-major), add them up, and come up with a far-more-accurate figure for annual regulatory costs. If agencies have to do annual budgets, and regular audits of their books and business practices, then they ought to also report on what impact they're having to the economy at large.

**10. Mandate that New Rules Assess Not only Cumulative Regulatory Costs for Small Business, But Present Those Costs in the Context of their Overall Regulatory Burden:**

**Burden:** We believe this is critical. If we all agree that it is not just “major” rules, but the incremental costs of all rules that create this burden for small business, then we have to assess costs within context. Agencies are forced to continuously restate the burden that they already impose, and have to then show how they are about to add to that burden. This ought to be done in a variety of metrics as well: dollar costs, costs in man-hours, costs in days lost.

**The Business Gateway: Helping Businesses Learn How To Comply**

NFIB takes a different approach towards simplifying the methods by which small businesses learn what regulations they are obligated to comply with, and how they ought to comply. To its credit, the federal government has recognized that technology can provide a number of solutions to the federal regulatory and paperwork burdens. Two separate tracks, very different, and important in their own way, are being pursued: one dealing with increasing participation and making the formulation of rules more streamlined (e-docketing); the other meshing technological tools with the problem of regulatory understanding, compliance, and paperwork burdens (the Business Gateway).

It is unfortunate that the federal government initially got their priorities backwards, focusing first on e-docketing and e-democracy rather than putting more resources towards the Business Gateway. NFIB supports the federal government in attempting to open up the regulatory process to more perspectives—e-docketing promised to make it easier for small businesses and individuals to offer their thoughts on proposed rules. By offering a “real world” perspective, career civil servants can make regulations that are smarter and more meaningful. What’s more, electronic docketing is an excellent tool for those doing the regulatory decision-making, in that it makes it easier for regulators to break down and analyze comments.

But as discussed earlier, the problem is that too many small businesses are spending too much time doing federal paperwork already, and it is simply too much to ask of them right now to take additional time and resources to comment on a complex regulatory proposal. Sure enough, there are some businesses and individuals that will comment, and the regulatory state can only benefit from their expertise, but the executive branch must reduce burdens elsewhere if they hope to invest a more substantial set of the population in the rulemaking process.

This is why we believe that more resources should have been directed earlier on to the Business Gateway project (once called the “Business Compliance One-Stop” or BCOS). The Business Gateway is a good step in this direction, and a greater emphasis must be placed on the continued development and implementation of this system, and NFIB is heartened that the second generation of this project came on line in October of 2007 (NFIB has been and will continue to be an active participant in the development and implementation of this program).

Everyone involved in regulation: the regulated community, activist stakeholders, members of Congress and their staffs, the federal agencies and their personnel, all must ask the same question—what is it that we want from the regulated community, in the end?

The answer, at least in our estimation, is simple: we want the regulated community (again, our members and the small-business community as a whole) to understand its responsibilities when it comes to regulatory compliance and comply with those regulations that apply to them. What’s more, our members want to be in compliance with the law. They want to keep their workers and their communities safe and secure, and the last thing they want is for a government inspector to show up at their offices and fine them for some transgression.

Unfortunately, the regulatory state is so complex (consider in your minds, for a moment, the wide expanse that is the Code of Federal Regulations, and just what a small-business owner would need to do to figure out his responsibilities) that it is next-to-impossible for any small business to be in compliance with all of the regulatory requirements he faces .

But imagine a system in which a small-business owner could enter some simple information about his business: his industrial classification code, a zip-code, number of employees, etc. As discussed above, 92 percent of small businesses have computers, most with internet access (the majority of it high-speed), so the vast majority of businesses could do this if they so chose.

Then the system takes that information and spits out each and every regulation that applies to this business, along with simple compliance information. It would be even better if this system could

provide an on-line access for small businesses to submit forms, should they choose to submit them that way (the operative word being “choose” – not mandate).

Yes, this is an ambitious idea. But in an era in which huge databases can be accessed from thousands of miles away in a safe, secure and fast manner, it is not an impossible task. The current iteration of the Business Gateway, Business.gov, is a solid step in the right direction. But it must do more, far more, in terms of offering a simple way for businesses to determine what their regulatory responsibilities are and to make living up to those responsibilities as easy as possible. NFIB looks forward to seeing the next iteration of Business.gov in October, as well as each and every iteration of it, as it moves towards the full-measure of what it ought to be.

What it will take is leadership from Congress: funding, oversight, and the political will to see it happen.

If Congress is serious about reducing paperwork, then it must do something about making the fully-functional, fully-realized Business Gateway a reality. Once that is established, businesses know their responsibilities, and compliance is made as simple as possible, then businesses will not only have the time and resources to devote to helping the government craft smarter regulations, they will have an incentive to be invested in the process.

Not all businesses would do it (not all businesses have computers), so the option to find out about regulations in the traditional manner would still have to be in place. In fact, there are a number of small businesses that will never be on computers<sup>14</sup> (which is why NFIB continues to advocate for the position that when agencies desire to work with the public via computers, it is a voluntary and not mandatory program). But such a system would be far superior than that which is available to small-business owners today, and a tremendous leap in seeking greater regulatory compliance.

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<sup>14</sup> In fact, in recent conversations with NFIB field personnel, I learned that our organization has a number of members who are Amish small-business owners. Clearly, these are small businesses that will never be using computers in their daily work, and any move to make computer communications mandatory (or any other sort of mandatory electronic interaction) would be grossly unfair to them.

Until then, however, the benefits of technology, whose primary purpose is e-docketing, accrue mostly to those who work in government.

#### The Intermediate Step

While we believe that the Business Gateway will be a tremendous tool for truly improving compliance and reducing burdens on small businesses, we recognize that there are a number of interim steps that will need to be taken, steps that will also require tremendous leadership on the part of the Congress.

Success of the Business Gateway will hinge on the quality of the information it provides: simple explanations and easy-to-understand-and-follow step-by-step instruction on how to comply. This means a wholesale restructuring of the information that is conveyed to the public: a comprehensive review of all regulations mandated by the agency, the review of all guidance documents, manuals, and other publications the citizenry uses to determine what their obligations are and how to go about them.

Then the agency will have to start building from the ground up: creating plain-language guides to each of their regulatory regimes. Guides that are as short as possible. Guides that are easy to find, take a common-sense approach to compliance, walk small business owners or their employees through the compliance process, and offer them clear suggestions in what they ought to be doing to be in compliance with that particular regulation.

There are no two ways about it: this will be a Herculean task. Nevertheless, it must be undertaken. Heretofore, the agency has balked at such reviews, and it's not difficult to understand why. They get no credit for it, simply put. Why put resources into developing easy-to-understand compliance guides when Congress and activist stakeholders are going to ask them why they didn't spend more resources on investigations and prosecutions.

So it is thus incumbent upon Congress to give the EPA the support it will need to do this. What is important is that in the near term, before the Business Gateway is in its final form, the Agency

will be developing useful tools that can be utilized by small businesses as soon as they are made available.

**Conclusion**

There are many metaphors used to describe how incremental costs can have catastrophic results, like “the straw that broke the camel’s back.” Or how an individual feather can weigh next-to-nothing, but a ton of feathers still weighs the same as a ton of bricks.

The same holds true with regulation. A single regulation, taken in isolation, might have virtually no cost. But the body of regulation costs the American economy over a billion dollars annually. A single federal paperwork mandate might take fifteen minutes. But all told, these mandates take over **8 billion** hours.

Something has to be done. Congress has to step in and take a look at both the continued regulatory burden that pours out of federal agencies, focusing on tailoring new regulations that harm small business, changing regulations that are already on the books, and working with the agencies to assess costs and create good tools to help small businesses fulfill their obligations under the law.

Thank you again for the opportunity to testify. I look forward to answering any questions you might have.



**Written Testimony of Charles B. Sewell, Senior Vice President of Government Affairs for the  
National Community Pharmacist Association**

**December 6, 2007**

**Hearing before the House Committee on Small Business Regarding Legislation to Improve the  
Regulatory Flexibility Act**

Good Morning, Madam Chair and other members of the Committee. Thank you for conducting this hearing and providing us an opportunity to share our support and recommendations for this legislative proposal to improve the Regulatory Flexibility Act ("RFA").

My name is Charles Sewell, Senior Vice President of Government Affairs for the National Community Pharmacists Association, or NCPA. I am honored to testify today on behalf of our members, their employees, and most importantly our patients. NCPA represents the nation's community pharmacists, including the owners of more than 23,000 pharmacies, with 75,000 pharmacists, over 300,000 employees and millions of patients who rely on us for their prescription care.

Independent pharmacists provide vital prescription services in rural, inner-city and urban areas, including services offered almost exclusively by independents, such as compounding, medication therapy management, durable medical equipment and home delivery. The nation's independent pharmacies dispense nearly 40% of the nation's retail prescription medicines.

Because of the face-to-face relationship with their local independent pharmacist, patients are more likely to take their medicines on-time, more likely to take them properly, more likely to refill meds before they run out and more likely to avoid harmful drug interactions. Patient access to their trusted independent pharmacist helps to lower health care costs by promoting patient health every day.

We are also small businesses, with small profit margins that suffer disproportionately from unnecessary administrative burdens. NCPA therefore applauds the initiative of this Committee in holding the November 15 hearing on the burdens of the Regulatory Flexibility Act (RFA) upon small business and drafting legislation to amend the RFA to improve its protection of small business in the face of government agency action.

Government is the independent pharmacist's largest partner as the Medicare Part D and Medicaid programs cover an average of half of our prescription volume. A robust RFA is therefore important to our success. Simply put, the Regulatory Flexibility Act was created to ensure that government agencies must examine the impact of their actions on small business and make their findings public. As the Committee knows all too well, this vital oversight and transparency help to preserve the small businesses which are the backbone of our economy.



From our perspective, the Regulatory Flexibility Act should serve as a shield for small business from the adverse effects of government agency actions. It is an absolute imperative that real economic analysis of small business impact is taken into consideration before a government agency implements new public policy.

**NCPA PROPOSALS:**

We support the draft "Small Business Regulatory Improvement Act of 2008", including its major provisions which:

- 1) Clarify when agency reviews of existing rules are to take place;
- 2) Require agencies to consider indirect impacts to small business; and
- 3) Codifies Section 3 of Executive Order 13272 (August 13, 2002) which require agencies to notify the SBA Office of Advocacy of proposed rules that may impact small businesses before such rules are published in the Federal Register.

These are sensible and helpful reforms. We believe, however, that they can be strengthened and be made to have an even greater potential impact.

**The three major reforms that we support are:**

- 1) For at least all major rules, an agency may not issue a final regulation unless it specifically analyzes the "significant impact" that implementation of the rule will have on small businesses. Agencies should not be able to hide behind the excuse of having a "lack of evidence." In order to proceed, agencies must affirmatively demonstrate that there is no significant adverse impact on small business. If studies exist which show the rule will cause a significant impact, the agency cannot simply dismiss the studies and proceed with implementation.
- 2) Once there is a finding of significant impact upon small business, the agency should not be able to implement the rule for the small business sector.
- 3) A private person or entity or governmental entity can make a regulatory challenge of an agency that releases a final rule which the person or entity believes was done in violation of the RFA. The regulatory challenge would be an abbreviated administrative action adjudicated through the SBA. Failure to obtain relief in the SBA process would not preclude the challenger from filing a subsequent, nor would it negate a simultaneous lawsuit.

NCPA believes from its experience with government agencies that such strong measures are necessary to ensure that agencies truly examine the impact of their actions upon small businesses.

A recent and key example is the final CMS rule implementing the Medicaid reimbursement provisions of the Deficit Reduction Act of 2005 (DRA). The DRA and subsequent regulatory rule will be devastating to community pharmacy. CMS, however, used a technical reading of the DRA to



ignore the significant economic impact of the rule upon pharmacies under both HHS and SBA standards.

**INDEPENDENT PHARMACIES ARE VITAL AND VIBRANT PARTS OF THEIR COMMUNITIES AND ARE SMALL BUSINESSES THAT HAVE BEEN HARD HIT BY MEDICARE PART D AND WILL BE FURTHER DAMAGED BY IMPLEMENTATION OF THE FINAL RULE BY CMS**

Through attentive patient care and dedication to their communities, independent pharmacies have been able to compete with chains and mass merchants. In fact, the independent pharmacy sector was quite stable in the 5 years prior to Medicare Part D. Independent pharmacists have considerable staying power: A full 68% have been in business for more than 20 years.

**Pharmacies are closing: Part D and CMS' AMP**

In 2006, however, 1,152 independent pharmacies were sold or permanently closed. This net loss of three independents per day is directly attributable to Medicare Part D, chiefly from payment delays, lower reimbursements, and patients being unfairly steered into mail order and away from their community pharmacy.

It can easily be said that the Federal government maintains the controlling interest in the operation of every independent pharmacy. This is not by our choosing. Between Medicare and Medicaid, the average independent will see half our patients' care controlled by government programs.

The giant Pharmacy Benefit Managers or PBMs who administer the Part D program have long used their size and market power to foist take-it-or-leave-it contracts upon independent pharmacies. Medicare Part D has tremendously strengthened the big PBMs. All Medicaid prescriptions for dual-eligibles are now paid by PBMs under Part D. The government and third parties now dictate the reimbursement for 92% of all retail prescriptions.

This level of third-party involvement, especially the share controlled by government programs, means that any regulatory changes will have a great impact upon the health and welfare of small business independent pharmacy. RFA was intended specifically to ensure small businesses in this position are not adversely impacted by government action.

To make matters worse, CMS has just published the final rule on Average Manufacturers Price, or AMP. AMP will serve as the new reimbursement basis for the Federal Upper Limit (FUL) on generic drugs dispensed under the Medicaid program. These changes were among the many onerous provisions of the Deficit Reduction Act of 2005.

The original purpose of AMP was to serve as an index for manufacturer's rebate liability. CMS acknowledges that their AMP will now serve these two distinct purposes, but fails to reconcile the definition of AMP so that it is appropriate as an accurate benchmark for reimbursement. CMS

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also did not include any policing of manufacturers calculating or reporting process thereby giving manufacturers the opportunity to minimize their rebate liability by underreporting AMP.

CMS' AMP is simply not appropriate for pharmacy reimbursement. Period.

The DRA sets the new FUL at a maximum of 250% of the lowest AMP for therapeutically equivalent and nationally available generics. This 250% is a best-case scenario as some states will likely set reimbursement below the FUL. The HHS Office of Inspector General recently reported that even with the 250% multiplier, the FUL would still fall below pharmacy acquisition cost for 19 of the 25 high-expenditure generic drugs studied. For 5 of the other 6 drugs in the study, the pharmacy would only cover the cost of the drug, but would still realize a loss once the cost-to-dispense is considered.

Retail pharmacy cost-to-dispense averages \$10.50 nationwide according to a 2007 study by the international accounting firm Grant Thornton. The dispensing fee paid under state Medicaid programs is far lower at an average of \$4.50. When these numbers are applied to the findings of the OIG study, only 1 of the top 25 high-expenditure Medicaid drugs would post a meager profit under the new FUL.

These findings are consistent with those of a December 2006 GAO study (released January 2007) which found that the new FUL would fall below acquisition cost for 59 of the 77 generics profiled. The AMP-based FUL was 65% below acquisition cost for the 27 high-expenditure drugs studied, 15% below acquisition for the 27 most-frequently prescribed generics, and an average of 36% below pharmacy acquisition cost across the entire sample.

CMS has disputed the findings of both reports; however, the methodologies used by each agency are congruent with provisions contained in the rule. CMS failed to refute any of the report's specific findings, instead relied on sweeping generalizations to dismiss two independent government agency reports as flawed and irrelevant. The HHS Secretary also totally rejected the GAO study during testimony before the House Committee on Energy & Commerce without providing any specific refutation of the study's findings.

No economic analysis of the impact on small business pharmacies was ever really conducted by CMS despite overwhelming evidence. This is proof as to why the RFA should be amended to allow affected parties the opportunity to challenge agencies as they issue rules which impact small business.

**THE UPCOMING SIGNIFICANT IMPACT UPON INDEPENDENT PHARMACY AND  
CMS' CURSORY DISMISSAL OF THAT IMPACT SHOW THE NEED TO ADOPT  
NCPA'S SUGGESTED REFORMS**

In both its proposed and final rule, CMS failed to examine the negative impact the rule would have upon community pharmacy – and in particular upon independent community pharmacy. Instead, CMS states in its final rule (CMS-2238-FC):

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. . . we are unable to estimate quantitatively effects on “small” pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. We received general comments that these pharmacies will be greatly impacted by the provisions of this rule; however, we did not receive documented estimates of these effects. Because of the lack of evidence as to the true effect, we have retained our prior conclusion that this proposed rule is likely to have a “significant impact” on some pharmacies. *Federal Register, Vol. 72, No. 136, July 17, 2007 at 39233 [CMS refused to provide the industry with AMP data to review]*

We estimate that 18,000 small retail pharmacies will be affected by this regulation. *Id. at 39234.*

CMS has shirked its responsibilities under the Regulatory Flexibility Act’s requirement for analysis of significant economic impact by not analyzing that impact in either its proposed or final rule. CMS has admitted that there will be a significant impact upon small pharmacies, yet it has twice chosen not to analyze that impact because it was not presented with “documented evidence.” OIG and GAO have both documented the “significant impact” upon community pharmacy, yet CMS continues to contend that the impact cannot be determined. NCPA believes that CMS has violated at least the spirit and intent of the Regulatory Flexibility Act. **Under NCPA’s proposed additions to the “Legislation to Improve the Regulatory Flexibility Act”, CMS would be violating the letter of the RFA.**

It is CMS’ position that under the Regulatory Flexibility Act and the standard for HHS regulations, CMS is required to analyze the impact upon small businesses if implementation of the regulatory rule will result in a negative impact upon gross revenues of 3% or more. For the case of AMP, CMS looked at the impact on prescription drug revenues. Even if one accepts this standard, based on data from the 2007 NCPA Digest, the rule will have at least that amount of impact upon the median independent pharmacy. The impact will be greater upon rural independent pharmacies and those independent pharmacies serving a higher than average number of Medicaid patients.

**Even under HHS/CMS’ high standard of loss of gross revenues, those projected losses under CMS’ AMP demonstrate that CMS should have found a significant impact**

More than 50 percent of the business of some ten percent (10%) of independent pharmacies is from Medicaid, with the majority of those prescriptions being filled as generics. The average amount of Medicaid business for an independent pharmacy is 14%. These independent pharmacies and their patients will be disproportionately affected.

The total revenue from generic Medicaid prescriptions is low relative to the total median independent pharmacy business because generic drugs are significantly cheaper than brand name drugs. (based on CMS data from January to June 2006, the average prices paid for a generic and brand name drug under Medicaid are \$21.92 and \$155.98, respectively). Because profit margins are higher with generic drugs, the implementation of the rule will affect independent pharmacists to a much greater degree than might be assumed based on gross revenue calculations. More importantly,



reimbursements below acquisition costs will depress generic utilization rates, leading to higher costs as more brand name drugs are dispensed. This shift will ultimately hurt taxpayers.

Any revenue projections must assume that all other prescription sales and non-prescription sales will stay constant after implementation of the rule. This is an assumption made not in the belief that all other sales will stay flat, but rather for the sake of making as uncomplicated a calculation as possible. In reality, for those stores that can stay in business, a loss of Medicaid patients would mean, for example, a loss of those patients that also acquire diabetic and related Medicare Part B supplies. The impact upon the business is difficult to measure, but it surely must reach beyond the linear loss of Medicaid generic drug reimbursements.

**More importantly, the dramatic loss of net profits (SBA standard) under CMS' AMP is unacceptable and further supports the needs for NCPA's proposed reforms**

Under Small Business Administration (SBA) standards, CMS can and should have considered the effect on profits of small pharmacies by the proposed and final rules. Under that standard, it is even clearer that small independent pharmacies will suffer significant economic impact under the final rule.

SBA standards for implementing Executive Order 13272, which President Bush signed on August 13, 2002, (reassigning responsibility of duties under Executive Order 12866), gave new direction for federal agencies in their efforts to assess the impact of their proposed rulemakings on small business and other small organizations under the Regulatory Flexibility Act, and directed the SBA's Office of Advocacy to provide agencies with information on how to comply with the President's directive. In that rule, the SBA directed federal agencies to look to the impact upon profits of small entities caused by a new rule.

Under the standard of impact upon profits, small independent pharmacies will indeed suffer significant economic impacts which CMS acknowledged, but did not analyze. Once again, assuming that all other prescription and non-prescription sales would stay constant, implementation of the final rule would cause the total net profit of the average independent pharmacy to fall by nearly 80%. No business can stay in business for very long without making at least a small profit.

**CMS did not take into account the resulting harm to the Medicaid program, beneficiaries and taxpayers**

The new FUL will force states to underpay pharmacies for many generic drugs. This will in turn force pharmacies from the Medicaid program and severely reduce patient access. Many independents will close their doors entirely. We expect to lose over 2,300 pharmacies with high Medicaid volume (over 50%) almost immediately when this CMS scheme goes into effect.



## **CONCLUSION**

NCPA thanks the committee for the opportunity to discuss with it the inadequacies of the current RFA. In analyzing the impact of its implementation of the DRA, CMS took advantage of a technical reading of the RFA to ignore the significant economic impact that implementation of the rule will have under both the logical SBA standard of loss of profit, and also under the broader HHS/CMS standard of loss of gross revenue.

This testimony discusses just one example of a government agency subverting the positive public policy intentions of the Act. In order to protect the interests of small businesses and the communities they serve, NCPA requests that in addition to the reforms contained in the draft "Legislation to Improve the Regulatory Flexibility Act", the Committee support and introduce three other reforms, previously detailed and now summarized below:

- 1) **For at least all major rules, an agency may not issue a final regulation unless it specifically analyzes the "significant impact" that implementation of the rule will have on small businesses.**
- 2) **Once there is a finding of significant impact upon small businesses, the agency may not implement the rule as it applies to the affected small business sector.**
- 3) **A private person or entity or governmental entity can make a regulatory challenge of an agency that releases a final rule which the person or entity believes was done in violation of the RFA.**



December 6, 2007

The Honorable Nydia Velázquez  
 Chairwoman, House Small Business Committee  
 U.S. House of Representatives  
 Washington, D.C. 20515

The Honorable Steve Chabot  
 Ranking Member, House Small Business Committee  
 U.S. House of Representatives  
 Washington, D.C. 20515

Dear Chairwoman Velázquez and Ranking Member Chabot:

On behalf of Associated Builders and Contractors (ABC) and its more than 24,000 general contractors, subcontractors, material suppliers and construction related firms across the United States, I would like to take this opportunity to thank you for holding today's hearing on "Legislation to Improve the Regulatory Flexibility Act". I am also writing to re-affirm ABC's position on the increasing need for regulatory reform. Through your leadership, it is our hope that regulatory reform is addressed in a meaningful manner during the 110<sup>th</sup> Congress.

The majority of ABC members are small businesses and struggle with the heavy burdens of federal regulations on a daily basis. Many regulatory mandates appear to have little benefit in ensuring a safe and healthy worksite. The construction industry is one of the most highly regulated industries in our economy. Regulatory reform efforts are most often thwarted by claims from the labor and environmental communities who claim that "scaling back" regulations will result in harming the health and safety of the nation by gutting programs and protections. In reality, efforts to reform government regulations are designed to ensure that public and private resources are spent more effectively and efficiently while also working to achieve a cleaner, safer, healthier environment.

When addressing regulatory reform ABC strongly believes Congress should consider the following:

- Enforcement of our nation's goals works best when it is performed at the local level and provides necessary flexibility. Costs involved in policing the regulatory

state brought the total burden of regulations to \$754 billion in 1998. This is an astronomical monetary burden to be shouldered by America's small businesses.

- The government should be required to conduct an accurate assessment of the costs and benefits of proposed regulations on the public and be held accountable through congressional scrutiny. This will better allocate limited resources and target efforts toward achieving the nation's environmental, health, and safety goals.
- Regulations should be reviewed periodically to ensure that they are not outdated, unnecessary, or too costly. It is common sense that American citizens should not be forced to live by burdensome or inappropriate rules that are not justified for current times.

For the construction industry, excessive regulation translates into higher costs that are eventually passed on to the consumer. Over-regulation on public sector contracts costs the federal government and taxpayers millions of dollars per year. Extreme regulation places an additional burden on the nation's economy by increasing cost of doing business.

ABC recognizes the importance in addressing regulatory reform so that small businesses are not inundated with needless, and often detrimental, regulations. Thank you for your attention to this critical issue.

Respectfully submitted,

*William B. Spencer*

William B. Spencer  
Vice President, Government Affairs

CC: Members of the House Small Business Committee

